IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, *et al.*,
Petitioners

v.

GLEN L. RUTHERFORD, *et al.*,
Respondents

On Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

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BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN SUPPORT OF PETITIONER, THE UNITED STATES

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BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN SUPPORT OF PETITIONER, THE UNITED STATES

STATEMENT OF INTEREST OF THE AMERICAN CANCER SOCIETY

The American Cancer Society has a substantial intrest in the outcome of this proceeding. Briefly stated, the American public and the medical profession look to the American Cancer Society to provide the most up-to-date and accurate information about cancer. Since early and effective treatment of cancer is a life and death

matter, one of the areas in the forefront of the public and professional questioning addressed to the Society pertains to unproven methods of cancer treatment. In its efforts to respond to the need for information in this area, the Society established a committee on unproven methods and maintains one of the largest reference centers for the collection and dissemination of data concerning the subject. In furtherance of its obligation to the American public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated in the Food and Drug Administration rulemaking proceeding which followed the legal parameters set by the Court of Appeals in *Rutherford* v. *United States*, 542 F.2d 1137, 1140-43 (10th Cir. 1974). (Petitioners' Appendix at 51d). The Society also participated as amicus curiae in the proceedings on appeal which are the subject of this petition. (Petitioners' Appendix at 10a).

The outcome of the Government's appeal which the Society supports will be largely determinative of whether the protections provided by Congress to the American public in the Food Drug and Cosmetic Act will survive or whether they will fall, depriving both the consumer and the practicing physician of the first line of defense established by Congress at the request of President Kennedy who stated:

> There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . ineffective drugs.
>
> The physician and consumer should have the assurance from an impartial scientific source, that any drug or therapeutic device on the market today is safe and effective for its intended use . . . .

1962 U.S. Code Cong. & Admins. News at 4143-44. Either the impact of the *Rutherford* Court of Appeals decision,

which writes off the safety/efficacy provisions of the federal drug laws as they apply to the terminally ill, or the impact of the alternative grounds for decision of the district court, which finds both a grandfather clause exemption for Laetrile and a right of privacy in its use, will obviously affect the Society in its role as primary information source to the general public and the medical profession for accurate information on unproven methods of cancer treatment.

Should the *Rutherford* decision stand, another indication of its impact on the public, and the Society as its information resource lies in the resurgence, since mid-1976 when the *Rutherford* suit became heavily publicized, of inquiries about a number of unproven methods of cancer treatment in addition to laetrile. Prior to the *Rutherford* publicity, some of these methods were quiescent for months or years or came to the Society's attention at long scattered intervals. Those unproven methods include, e.g., the biological theory of ionization; wobe mugos; herbal remedies such as one called essiac; chelation therapy and alleged vaccines combined with special diets.

By way of specific illustration, a complaint for forfeiture is pending before a district court in California [1] involving:

> "Wobe Mugos products in the treatment of Cancer, Herpes Zoster and Herpes simplex; and
>
> Wobenzym preparations in the treatment of cancer, arteriosclerosis, angina, asthma, arthritis, bursitis, circulatory disorders including diabetic circulatory disease, intermittent claudication, phlebitis and thrombophlebitis, varicose ulcers, pneumonia, cysti-

[1] United States v. Articles of Drug consisting of . . . WOBE MUGOS Lozenges, No. CV 78-3736 AAH(KY) (United States District Court, Central District of California) (September 28, 1978).

tis, emphysema, and gynecological and urological inflammatory disorders."

If the Court of Appeals' decision is permitted to stand, it will open the floodgates and permit the public, particularly those with life-threatening illness who are choice prey, to be inundated by worthless and therefore unsafe and dangerous drugs. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interests which currently exists in the statutory scheme relating to drugs. It would be a grave disservice to the public if this regulatory scheme were undermined on the basis of a Court of Appeals or on the alternative grounds advanced by the district court opinion which we demonstrate below is unsound as a matter of law.

The American Cancer Society has received the consent of counsel for all parties to file this brief *amicus curiae* in accordance with Rule 42 of this Court. Those permissions are attached to the original of this brief filed with the Supreme Court.

SUMMARY OF THE ARGUMENT

The court of appeals exemption of the terminally ill from the pre-marketing requirements of the federal drug laws. The plain language of the federal drug laws does not signal any exemption from coverage for the terminally ill. To the contrary, the legislative and administrative history of those laws and their interpretation by the courts show a specific intent to safeguard consumers with life-threatening and terminal illnesses. The holding of the court of appeals exempting the terminal from these pre-marketing clearance provisions runs against this intent and also contra to the decisions of other federal courts who, faced with drug law challenges by a patient class of the terminally ill, have held these laws applicable to that class. Further, although it is theo-

retically possible to formulate a definition of terminally ill, the objective application of that definition is improbable. The record in this proceeding shows abuses which will permit other than those certified as terminally ill to have access to laetrile and those abuses have also surfaced in other proceedings in federal and state courts. Finally, the public interest requires application of the premarketing clearance requirements of the federal drug laws for the benefit of all consumers including the terminal. When the nebulous benefits of access to a drug generally recognized to be ineffective and unsafe to the in-fact terminally ill, those with only a few weeks or months to live, against the very real threat of exemption and broadening of access to those whose cancer is in the early stages, treatable and merely life-threatening.

The district court's application of the 1962 grandfather clause. The district court improperly shifted the burden of proceeding and proof in the rulemaking proceeding from the drug proponents on whom its properly rests to the Food and Drug Administration. However, even under the improperly shifted burdens of proof, the record establishes the error of the district court exempting Laetrile from the premarketing requirements of the federal drug laws by application of the 1962 grandfather clause. Laetrile does not satisfy the grandfather clause requirements of (1) consistency and predictability in drug formulation, dosage, route of administration, mechanism of action, claims and conditions for usage and effect; (2) its use prior to 1962 was investigational and not commercial; and (3) it is not generally recognized by qualified experts in cancer treatment as safe or effective. Where life-threatening illness is involved the administration interpretation of "safety" under the 1938 Act period included toxicity and effectiveness. This administrative interpretation was adopted by Congress when it considered the 1962 Drug Amendments and thus Laetrile must be generally recognized as effective as well as

safe (non-toxic) before it can receive the exemption contemplated by the 1962 grandfather clause.

The district court's holding that laetrile use in personal health care is protected by the Constitution. An analysis of this Court's decisions regarding "privacy" in the context in which they were rendered shows that the selection of a particular drug or medical treatment procedure is not invested with privacy status. The decision whether to receive medical treatment may be constitutionally protected but the choice among treatment alternatives is not within the scope of any right recognized by this Court. Further, if a privacy right is found by this Court, the nexus of the premarketing provisions of the federal drug laws with the preservation and protection of the health of the cancer patient justifies government regulation under both the rational relationship and compelling interest tests.

ARGUMENT

I. THE COURT OF APPEALS REVISION OF THE FEDERAL DRUG LAWS TO EXEMPT THE TERMINALLY ILL NOT ONLY FLIES IN THE FACE OF CONGRESSIONAL INTENT BUT ALSO EFFECTIVELY DEPRIVES THOSE WITH LIFE-THREATENING ILLNESS OF THE PROTECTIONS OF THE ACT

A. Overview of the Problem

The Court of Appeals did not address the issues of whether Laetrile was generally recognized as safe and effective among qualified experts, nor whether it is grandfathered, nor did it address the additional ground of decision advanced by the district court—the alleged Constitutional right to privacy. Rather, the court of appeals held "as a matter of law that the 'safety' and 'effectiveness' requirements of the statute as now written have no application to terminally ill cancer patients who

desire to take the drug [Laetrile] intravenously." (Petitioner's Appendix 7a, hereinafter stated as "Pet. App."). This holding has a surface appeal. If a person is going to die, why not indulge him by permitting access to any alleged cancer remedy he may wish to try. The reasons for denial of such permission are many.

The court of appeals assumes that an objective standard is available or can be formulated and applied to determine who is "terminally ill." This assumption is in conflict with the findings made by the Commissioner in the Laetrile decision, (Pet. App. at 267a-270a). The thrust of those findings is that cancer is a disease that affects individual patients and that physicians dealing with these patients on an individual basis find it difficult to distinguish the in-fact terminal from non-terminal cancer patients with any accuracy. The practical and ethical problems of carving out an exception for the terminally ill from the Act was pointedly addressed by Dr. Samuel Klagsbrun in his affidavit (Ad. R. 433).[2]

> Use of the term "terminally ill" is inappropriate when dealing with an individual cancer patient. Although specific forms of cancer may have a statistically expectable mortality rate, that rate is meaningless when applied to an individual patient. Oncologists are all familiar with experiences where severe cancers, which were statistically considered to be hopeless, have, in some small percentages of cases, undergone a sudden remission. It would be tragic to condemn any individual cancer patient to

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[2] The record transmitted to this Court made a distinction between the record compiled during the Laetrile rulemaking proceeding and the record specifically developed before the district court. This distinction will be observed in the Society's brief. References to the administrative record will be cited Ad.R. —; or administrative transcript, Ad.Tr. —; references to the court record will be cited Ct.R. —; or if a district court hearing transcript is involved Ct.Tr. —.

death because, as a statistical matter, that patient's particular form of cancer may not be curable.

A decision to allow patients who are diagnosed as having a cancer which, as a statistical matter expected to lead to their death, would move all such patients away from orthodox therapy and condemn even the individual patient whose cancer may unexpectedly move into remission to Laetrile, a worthless and ineffective drug. In addition, such a decision would thereafter remove the patients from the possibility of receiving continuing chemotherapy or radiation therapy which could enhance the effects of any remission. Most physicians have undergone the experience of predicting the moment of death and have unexpectedly and repeatedly been proven wrong to a considerable degree. The prolongation of life, therefore, becomes a goal, not simply for the sake of prolongation, but also to render patients available to either a recent advance in chemotherapy or simply to enhance the quality of the time left available to the patients.

Even if we assume theoretically that the phrase "terminally ill" may be capable of objective application,[3] in practice, in the district court proceeding, tight objective standard criteria court proceeding, tight objective stand-

[3] Robert S.K. Young, M.D. (Ct.R. 210-211) indicated before the district court what he considered to be the criteria for determining whether a patient is terminal:

"a. There must be histologic evidence of a malignancy in the patient.

b. The malignancy must be characterized as a disease with a high and predictable mortality. It must also be rapidly progressive. The malignancy will result in death in a relatively short period of time, i.e., within a few weeks or within a few months."

c. There must be no treatment recognized by experts as safe and effective for the disease, or therapies recognized as safe and effective for the disease have been totally exhausted, and further treatment would not be reasonably expected to benefit the patient.

ard criteria has been eschewed.[4] Instead, the district court proceeding employed an affidavit process that does not present a reasonable certainty that laetrile access will be confined to those who are in fact terminally ill.[5]

Further, the record in the district court, discussed in Section D hereto shows the abuse of the affidavit process to permit importation of laetrile far in excess of patient requirements to be disposed of to cancer patients who have not been certified terminally ill by affidavit.

[4] The FDA in its policy of the implementation of the affidavit process for access to laetrile put into effect by the district court to assume that the legitimately terminal alone were permitted access to laetrile, also required the patients affidavit subjects to possess a doctors affidavit that they will probably die within a few weeks or a few months and also to show proof that they had a medical exam within the last three months (Ct.R. 309-310). The Government contended that this would be the only way to assure that the patients receiving laetrile were in fact terminal (Ct.R. 315-316).

The rationale behind this information requirement was explained by Dr. Young at Ct.R. 331-334:

"The essential first step in making an accurate medical diagnosis of a malignancy, as opposed to mere speculation as to a patient's condition, is the obtaining of histologic evidence and characterization of the disease. This information compiled with a thorough physical examination and appropriate diagnostic laboratory tests including radiologic and scintillation studies and intimate knowledge of the natural history of the disease enables a physician realistically and reasonably to reach a conclusion as to whether a particular tumor can be characterized as one which is usually rapidly progressive and which, if untreated, normally results in a high and predictable mortality rate."

[5] The district court's reaction to this rationale was to add a condition that the date of examination be noted on the affidavit form (Ct.R. 337-338). Further, since the affidavit does not require a physician to refuse to execute the affidavit if orthodox modalities are not also employed or if other orthodox therapies of benefit are available but can justify execution on presence of progressive cancer plus informed consent, there is no assurance that only those without medical alternatives will legally import laetrile. See e.g., Ct.R. 481-484, 490, 493, 496, 499, 502.

In addition, a laetrile proceeding involving a minor, shows that the term "cancer" has been incorrectly treated as synonymous with "terminal" to obtain access to the drug. In the proceeding involving a minor, a physician has stated that even if he did not believe a patient terminal, he would so certify to assure the patient's access to laetrile.

These aspects of exemption and the effect of exemption on the larger class of cancer patients who disease is merely life-threatening are discussed in detail in Section D at pp. 23-33 *infra.* However, the most significant obstacle to the exemption created by the court of appeals springs from its absolute inconsistency with the intent of Congress as expressed initially in the Pure Food and Drug Act of 1906 and culminating in the 1962 Drug Amendments, discussed immediately below.

B. From the Exercise of Federal Authority Over Drugs Initially By The Act of 1906, And As Amended, The Terminally Ill Lay Within The Special Protection Of The Acts

The medical and popular press in the early 1900's reflected the sense of the country at that time that the words cancer and terminal illness were interchangeable. E. Cuyler Hammond, D.Sc., Director of Statistical Research Section of the American Cancer Society, writing in 3 Cancer 417 (Butterworth & Co., London, 1958) described the public's impression of cancer in the first quarter of this century as "incurable" and further stated that this conception was shared by a large proportion of the medical profession. This impression was certainly borne out by the literature which reported the survival rate for, e.g., uterine cancer in 1900, to be as low as 2.8%.[6]

[6] T.S. Cullen, Cancer of the Uterus (1900). See also, E.C. Hammond, "Cancer Prevention of Comparative Risks", 19 Archives of Environmental Health 395 (1969); and see J.S. Bloodgood, "Responsibility of the Medical Profession for Cancer Education, with Special Reference to Cancer of the Cervix", 15 American Journal of Cancer 1579 (1931) (cancer of the cervix is today predominantly a hopeless disease).

These statistics improved somewhat. Indeed, between 1935-1940, the five year survival rate for all sites of cancer combined reached 25%, by 1951 it reached 32%.[7] However, even in 1967, public and physician reaction to the term cancer still equated it with a death sentence:

> Cancer has many unconscious meanings and fantasies associated with it. Whatever the unconscious feelings which it stirs, typically it is feared consciously as a process equated with suffering and certain death . . . People continue to think of cancer as 'the killer.'
>
> What is impressive is that the doctors themselves feel very much the same way. It was not patients who described the diagnosis as a 'death warrant' or 'a date of execution.' The internist who referred to cancer as an 'incurable disease with an inevitable demise' expressed a view which was not atypical.[8]

As late as the summer of 1977, in Hearings before Senator Edward Kennedy's Subcommittee on Health and Scientific Research,[9] Lewis Thomas, M.D., Director of the Memorial Sloan-Kettering Cancer Center, observed that "For many patients and their families, the very word cancer is perceived as a death sentence. It is widely

[7] E.C. Hammond, "The Possibility of Improving Cancer Cure Rates at the Present Time", Cancer, May-June 1957 at 581-582; Proceedings of the Third National Cancer Conference 910 (1957).

[8] Donald Oken, "What to Tell Cancer Patients: A Study of Medical Attitudes", reprinted in Weir, Ethical Issues in Death and Dying (1977) at 21.

[9] Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, "Evaluation of Information on Which the FDA Based Its Decision To Ban The Drug Laetrile From Interstate Commerce", 95th Cong., 1st Sess (1977) ["Laetrile Hearings"].

believed to be an inexorable and agonizing process, with no way out but death." [10]

The early concern of the public and the press that the "seriously" or "terminally" ill be protected from useless nostrums is perhaps best exemplified by a series of articles by Samuel Hopkins Adams published in Collier's Weekly in 1906. These articles sought to enlighten the general public regarding the effects of various patent legislation regulation drugs.[11] A segment of the series contained the following passage, entitled, "Preying on the Incurables":

> Incurable disease is one of the strongholds of the patent-medicine business. The ideal patron, viewed in the light of profitable business, is the victim of some slow and wasting ailment in which recurrent hope inspires to repeated experiments with any "cure" that offers. In the columns of almost every newspaper you may find promises to cure consumption. Consumption is a disease absolutely incurable by any medicine . . . This is thoroughly and definitely understood by all medical and scientific men. Nevertheless there are in the patent-medicine world a set of harpies who, for their own business interests deliberately foster in the mind of the unfortunate sufferer from tuberculosis the belief that he can be saved by the use of some absolutely fraudulent nostrum. Many of these consumption cures contain drugs which hasten the progress of the disease . . . Others are comparatively harmless in themselves, but by their fervent promises of rescue they delude the sufferer into misplacing his reliance and forfeiting his only chance by neglecting those rigidly careful habits of life which alone can conquer the "white plague." One and all, the men who advertise medicines to cure consumption deliberately traffic in human life.[12]

[10] Laetrile Hearings, *supra* at 13.

This popular belief contrasts strongly with the actual statistics relating to survival from cancer due to earlier diagnosis and the steady improvement in surgical, x-ray and chemical approaches to the management of cancer. In the 1900's few cancer patients had any hope of long-term survival. In the 1930's less than one-in-five were alive at least five years after treatment. In the 1950's it was one-in-four. Now the ratio of patients alive after five years of disease is one in three. With even earlier diagnosis and prompt treatment, half of those who have cancer could be saved. See American Cancer Society, 1977 Cancer Facts and Figures, and see the 5 year survival statistics for specific sites of cancer when early diagnosis is made *infra* at note 30 which shows survivals of up to 86% of selected sites.

[11] See Cramp, Nostrums & Quackery (1912) for a compilation of the Colliers articles and a discussion of their effect on the food and drug legislation of 1906.

The inclusion of several of the Colliers Articles in the Congressional Record [13] and also numerous citations in the Pure Food and Drug Act debates of reported frauds perpetrated upon the victims of such serious illness as cancer, consumption and diabetes in the form of spurious claims for cures,[14] indicates a significant concern with those illnesses which in 1906 were "terminal" and by inference a determination by Congress that the "terminally ill" as a class would be protected by the legislation.

In face of this concern over the application of the 1906 Act to cancer, consumption and other illness which were then considered fatal, the Congress expressed disbelief when the Supreme Court in *United States* v. *Johnson*, 221 U.S. 488 (1911), a case which concerned a purported treatment for cancer, over a strong dissent by Justice Hughes, held that the 1906 Act did not apply to misrepresentations of facts relating to the ability of a drug to treat or cure a disease, but rather, only as to whether the ingredients used in the drug were properly stated on the label.

[12] 48 Cong. Rec., part 12, Appendix at 625-630.

[13] *Id.*

[14] See e.g., 40 Cong. Rec. 1416, 9073

In prompt response, President Taft, on June 21, 1911, in a message to Congress, urged action to protect the seriously ill against statements of curative effect on drugs that are contrary to fact and that seduce the ill away from proven medical treatments:

> An evil which menaces the general health of the people strikes at the life of the Nation. In my opinion, the sale of dangerously adulterated drugs, or the sale of drugs under knowing false claims as to their effect on disease, constitutes such an evil and warrants me in calling the matter to the attention of the Congress.
>
> Fraudulent misrepresentations of the curative value of nostrumes not only operate to defraud purchasers but are a distinct menace to the public health. There are none so credulous as sufferers from disease. The need is urgent for legislation which will prevent the raising of false hopes of speedy cures of serious ailments by misstatements of facts as to worthless mixtures on which the sick will rely while their diseases progress unchecked.[15]

The Congress reacted to this call for action by passing the Sherley Amendment to the Act [Act of August 23, 1912, 37 Stat. 416, ch. 352] which provided that misstatements regarding curative or therapeutic effects of a drug or device fall within the ambit of the Act.

In commentary upon the Sherley Amendments to the Act in the 1913 Report of the Bureau of Chemistry, Bureau Chief Carl L. Alsberg notes the early successes of the Amendment in terms of the curative claims found on medicinal labels. According to Alsberg, "Claims that preparations are cures for such serious diseases as tuberculosis or cancer do not appear on the labels as often as formerly." [16]

[15] 48 Cong. Rec. 11322 (1911). See also, Belmont Laboratories v. FTC, 103 F.2d 538 (3rd Cir. 1939).

The statutes extended protection afforded to those who suffer from untreatable or incurable disease is apparent from the opinion of Justice Hughes applying the Sherley Act Amendment to the 1906 Act in *Seven Cases . . . Eckman's Alternative et al.* v. *United States*, 239 U.S. 510, 514 (1916). Justice Hughes speaking for the Court, specifically upheld the following libel as a matter subject to prosecution under the Act as amended:

> [The label] conveys the impression to purchasers that said article or drugs will cure tuberculosis, or consumption, whereas, in truth and in fact, said articles of drugs would not cure tuberculosis, or consumption, *there being no medicinal substances known at present which can be relied upon for the effective treatment or cure of tuberculosis, or consumption.* (emphasis added).

The concern of Congress and the courts with the assurance that the federal drug laws protect those with terminal or life-threatening was closely followed in the administrative interpretation of the Act. The administrative interpretation [17] of the federal drug laws ex-

[16] Federal Food and Cosmetic Law, Administrative Reports, 1907-1949, CCH, Food Law Institute Series (1951).

[17] Hearings Before the Subcommittee on Antitrust & Monopoly, Senate Committee on the Judiciary, 87th Cong., 1st Sess. on the "Drug Industry Antitrust Act", Part 5 at 2588. (emphasis added)

In testimony before Congress, the FDA stressed that under its view of existing law, the safety of a non-toxic drug could be construed to include efficacy only where the disease involved is life-threatening. See S. Rep. No. 1744 (part 1) 87th Cong., 2d Sess. 15; H. Rep. No. 2464, 87th Cong., 2d Sess. 3. And see Hearings on Drug Safety Before a Subcommittee of the H. Comm. on Government Operations, 88th Cong., 2d Sess., pt. 1, 150, 183-186 (Commissioner Larrick) and Hearings on Drug Efficacy Before A Subcommittee of the H. Committee on Government Operations, 91st Cong., 1st Sess. 228 (Commissioner Ley).

To the same effect see Federal Food, Drug and Cosmetic Law Administrative Reports 1907-1949 at 927.

tend special protection to those with life-threatening or terminal illnesses. The FDA construed the language in the 1938 Drug Act, which required new drugs to show "safety", also includes "efficacy":

> It is important to recognize that evaluating effectiveness is not a new concept in the administration of the food and drug law. In some instances the decision as to safety of a new drug necessarily requires an evaluation of effectiveness. If the drug is offered for treatment of progressive or life threatening diseases, such as cancer, or if the drug is seriously toxic or has alarming side effects we now consider its effectiveness. In such cases the determination of safety is in the light of the purpose of the new drug provisions, inseparable from consideration of the drug's effectiveness." [18]

This prior administrative practice and its special, protective coverage for those with life threatening or progressive (terminal) disease was expressly recognized, endorsed and continued by Congress in the 1962 Drug Amendments.

> The Food and Drug Administration now requires, in determining whether a "new drug" is safe, a showing as to the drug's effectiveness where the drug is offered for use in the treatment of a life-threatening disease, or where it appears that the "new drug" will occasionally produce serious toxic or even lethal effects so that only its usefulness would justify the risks involved in its use. In such cases, the determination of safety is, in the light of the purposes of the new drug provisions, considered by the Food and Drug Administration to be inseparable from consideration of the drug's effectiveness. The provisions of the bill are in no way intended to affect any existing authority of the Department of Health, Education, and Welfare to consider and evaluate the effectiveness of a new drug in the context of passing upon its safety.[19]

Language in the debates on the 1962 Drug Amendments reflects an understanding that the Act would apply to experimental drugs used to treat "cancer in its last stages".[20] Senator Eastland, proponent of the bill, also assumed that drugs administered for "fatal diseases, such as cancer," would be subject to the Act's requirements, noting that approval of such drugs would be appropriate even though they might only prolong life or alleviate suffering.[21]

In view of this Court's interpretation of the amendments to the Act as progressively strengthening and extending that law's protection of the consumer,[22] and the continuing evidence of concern by Congress with diseases that were considered "fatal", the protection afforded terminally ill patients under the Act has even greater force and effect today.

The plain language of the Act,[23] its legislative history

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[18] Id. at 2588. See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609 (1973). With respect to the concern regarding cancer demonstrated in the debates on the 1938 amendments to the Act, see e.g., 79 Cong. Rec. 5023 (1935) (remarks of Sen. Copeland); 83 Cong. Rec. 7786-89 (1938) (remarks of Rep. Phillips and Rep. Lea). See also Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944.

[19] Drug Amendments of 1962, Senate Report No. 1744, July 19, 1962, 1962 U.S. Code Congressional & Administrative News at 2891-2892.

[20] 108 Cong. Rec. 17399 (1962) (remarks of Sen. Kefauver, Chairman of the committee reporting the bill).

[21] 108 Cong. Rec. 1740 (1962) (remarks of Sen. Eastland).

[22] See e.g., United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 793-99 (1969); United States v. Sullivan, 332 U.S. 689, 697 (1948); United States v. Dotterweich, 320 U.S. 277, 280-82.

[23] Section 201(p), 21 U.S.C. § 321(p) of the Food, Drug and Cosmetic Act provides in part:

[Footnote continued on page 18]

set forth above, the holding of this Court that the Act is to be given a liberal construction [24] and should not be narrowed in coverage "short of the point where Congress indicated it should extend",[25] all point out the error inherent in the court of appeals' decision which carved out an exception from the Act for terminally ill patients. The court has usurped the role of the Congress by rewriting the Act. The departure of the court of appeals from the role of the judiciary parallels a similar departure noted by this Court in *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969):

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. Strong indications from legislative history that Congress intended the broad coverage the District Court thought "ridiculous" should satisfy us that the lower courts erred in refusing to apply the Act's language as written. But we are all more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the

[23] [Continued]

> The term "new drug" means—(1) any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use and under the conditions prescribed, recommended or suggested in the labeling thereof.

[24] United States v. An Article of Drug . . . Bacto-Unidisk, 394 at 798. And see United States v. Lee, 131 F.2d —— (7th Cir. 1942).

[25] 394 U.S. at 801.

> public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety." Cf. United States v. Sullivan, 332 US 689, 693-695, 92 L Ed 297, 301, 302, 68 S Ct 331 (1948); United States v. Dotterweich, 320 US 277, 283-284, 88 L Ed 48, 52-53, 64 S Ct 134 (1943).
>
> 394 U.S. 798

C. The District And Appeal Court Decisions Conflict Markedly With the Decisions of Other Tribunals Presented With Patient Class Challenges To the Federal Drug Laws And Border on Pre-Emption

The Court of Appeals' conclusion "as a matter of law that the 'safety' and 'effectiveness' terms used in the statute have no reasonable application to terminally ill cancer patients, and have no established meaning when considered in that context" [26] is in conflict with *Rutherford* v. *American Medical Association*, 379 F.2d 641 (7th Cir. 1967), cert. denied, 389 U.S. 1043 [27] and also with *Tutoki* v. *Celebrezze*, 375 F.2d 105 (7th Cir. 1967).[28]

The *Allen Rutherford* case involved an action for a permanent injunction against the FDA and others by a physician and a number of cancer patients requiring that agency and others to cease their interference with the distribution, for their use, of the alleged cancer drug krebiozen. Krebiozen had not received new drug approval from the FDA and hence was unavailable in interstate commerce. The Court of Appeals "sympathetically viewed" the action as "an outcry of hopeless, suffering cancer victims." 379 F.2d. at 642. However, the Court

[26] Petitioners Appendix at 3a.

[27] Hereinafter referred to as the "Allen Rutherford" case to distinguish it from the Glen Rutherford case which is the subject of this proceeding.

[28] Hereinafter referred to as "Tutoki".

did not reach the conclusion that the Act does not apply to such "hopeless" cancer victims. It rather, in denying their claim for injunctive relief, held that the right to such relief requires a showing under the Act that under the procedures established by Congress for the introduction of new drugs, the drug Krebiozen would be approved or exempted (grandfather clause application) by the FDA.

In the *Tutoki* case, the court of appeals was asked to issue a declaratory judgment that the approval and exemption provisions of the federal laws relating to food and drugs do not apply to cancer patients and the drug they sought,—Krebiozen. 375 F.2d at 106. The *Tutoki* Court, specifically faced with the issue whether the federal drug laws were appropriately applied to cancer patients, mirrored the conclusions of the *Allen Rutherford* court,—that the FDA procedures cannot be bypassed unless it can be shown that the FDA, if it acted upon Krebiozen, who would have approved or exempted the drug.

The *Allen Rutherford* and *Tutoki* opinions thus postulate the provisions of the drug laws as applying to "hopeless" cancer patients,—the exact opposite of the result urged by the *Glen Rutherford* Court of Appeals.

A further ground for the reversal of the appeals court decision and adoption of the Commissioners decision lies in the nature of pre-emption. The impermissible conflict of the decisions of the district and the appeal courts with the federal drug laws. The legislative, administrative and court related history of the federal drug laws and amendments specifically articulate Congress' interest in protecting those with life-threatening illness or progressive (terminal) illness from drugs that are unsafe and ineffective. The *Rutherford* district court's certification of this case as a country encompassing class action, the legalization of laetrile in 19 states, the sham nature of the

affidavit system which permits those on the threshold of treatment easy access to a drug that has not satisfied recognized uniform standards of safety and efficacy all stand as obstacles to the accomplishment and execution of the full purpose and objectives of Congress in the establishment of uniform standards for drug access. *Cf. Ray* v. *Atlantic Richfield Co.*, —— U.S. ——, 55 L.Ed2d 179 (1978). A substantial amount of legislative history exists as early as the original 1906 Act of which the passage quoted below is representative, indicating an intent on the part of Congress that the federal drug laws establish uniform standards. Senator McCumber, a cosponsor of the Senate bill states:

> Another object is to prevent the evil of diverse rulings of the several commissioners of the States having pure-food laws . . .
>
> We well know, Mr. President, that the moment we do pass a general law upon this subject, by virtue of that law covering ninety-odd percent of all of the commerce in impure products, that law must become the dominant law; and, if there is any difference, the State laws will soon accommodate and modify themselves in conformity with the national legislation.

40 Congressional Record 1216 (1906) See e.g., 21 U.S.C. § 355 (new drug provisions) and compare with Section 202 of Public Law 87-781 which provides that the 1962 Amendments of the Federal Food, Drug and Cosmetic Act invalidates any provision of state law that is in "direct and positive conflict" with the Act.

It is well settled that a state is permitted to legislate or regulate with a view to the protection of its citizenry against fraud or imposition by impure or ineffective drugs. However, it is equally well settled that a:

> . . . state may not, under the guise of exercising its police power or otherwise, . . . enact legislation in

conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the acts of Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution.

McDermott .. Wisconsin, 228 U.S. 115, 131-132 (1912) (citations omitted).

The pre-emption rationale applies not only to states but also, to the orders of federal district courts. See rationale of Judge Chapman in his Order of November 30, 1976 in re *Julian H. Morgan, Sr.* et al. v. *David Matthews*, et al., Civil Action No. 76-1636, United States District Court of South Carolina, Spartanburg Division (appended hereto as Appendix A). The plaintiff cancer patients in the *Morgan* case, paralleling relief granted in some states by statute, sought to obtain civil, criminal and ethical immunity for physicians, nurses and technicians who would be administering laetrile. The plaintiff patients also sought a preliminary injunction restraining the federal officers from interfering with their procurement of a supply of Laetrile. In holding that the plaintiff cancer patients had not met their burden of satisfying the four criteria essential to the relief sought, Judge Chapman held that:

> Finally, it has not been shown that the granting of injunctive relief in this case would not injure other parties or the public. To the contrary, *to permit the distribution of Laetrile in this case would be to circumvent the laws enacted to assure that drugs distributed in interstate commerce be both safe and effective for their recommended use, and would undermine the ability of those charged with upholding these laws to do so most effectively in the future. Such a holding would also provide any future proponent of unproven remedies a basis for arguing to another court that it should allow the*

> *distribution of substances in a manner contrary to the law.* Appendix A at p. 6 (emphasis added).

D. The Harm Perceived To The Allegedly Terminal Patient By Withholding An Exemption From The Federal Drug Laws For Laetrile Is De Minimus Measured Against The Substantial Harm To The Class Protected By The Act Particularly Those Whose Cancer Is Merely Life-Threatening

Judge Chapman of the United States District Court for the District of South Carolina in *Julian H. Morgan, Sr. et al.* v. *Matthews, et al.*, Civil Action No. 76-1637, Order of November 30, 1976 (Appendix A hereto) denied a preliminary injunction sought by a person "suffering from the advanced stages of cancer of the prostate" to restrain federal officers from interfering with his procurement of Laetrile. He contrasted the lack of irreparable injury to the plaintiff cancer patient stemming from withholding access to laetrile with the injury to other parties and the public interest if the injunction were granted:

> It has not been shown that the plaintiffs will suffer irreparable harm if the injunction is not forthcoming. The only evidence presented to this Court of any benefit Laetrile might provide in the treatment of cancer is that in some instances individuals taking it "seem to experience diminishing pain and an increase in appetite, weight gain, and psychological improvement." Affidavit of Raymond Hilliard, M.D. This is consistent with the effect a placebo would produce. The record is devoid of any evidence that Laetrile cures or halts the progress of cancer. Thus, it does not follow that the enforcement of a law which denies Laetrile to a victim of cancer will cause him to suffer irreparable harm.
>
> * * * *
>
> This Court is not unmindful of the gravity of the situation facing those who are afflicted with cancer and of their desire to choose their own remedies in

> view of the absence of any known cure for this disease. However, granting the relief requested in this case could not only harm the public by weakening laws calculated to prevent the victimization of those afflicted with cancer and other conditions by playing on their desperation in the marketing of unproven and, possibly worthless remedies, but it could also further the growing tendency of those afflicted with this disease to engage in self treatment resulting in a delay in seeking early diagnosis and prompt treatment with forms of therapy that have no established value. The result of this type of delay could be disastrous, since early diagnosis and treatment is of the utmost importance in the management of cancer.

(Appendix A at pp. 5-7) (footnotes omitted).

Judge Chapman's concern that approval of laetrile for the terminally ill poses a substantial threat to those whose cancer is in a treatable stage is noted by Dr. Lewis Thomas at the Hearings held by Senator Kennedy on the Laetrile issue in July of 1977.[29]

> It is often asserted that since Laetrile is not a particularly toxic substance, it should be made available to all patients who wish to use it as a matter of free choice. There is, however, a very real danger here. If, for example, children with early leukemia or sarcoma, or women with cancer of the breast, or young men with Hodgkin's disease, are persuaded to give Laetrile a trial before doing anything else, the outcome will almost certainly be death, in circumstances where appropriate therapy could be life-saving.[30]

[29] Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, "Evaluation of Information on which the FDA Based its Decision to Ban The Drug Laetrile From Interstate Commerce", 97th Cong., 1st Sess. 14 (1977).

Similar objections to an exemption for the terminally ill were raised by David T. Carr, M.D. and made a part of the record in the Laetrile Rulemaking proceedings. Dr. Carr expresses his opinion concerning the medical and scientific basis for, and the public health consequences of the availability of amygdalin, or other similar unproven cancer remedies, for clinical use in patients with "terminal" cancer:

> My opinion is that this would be unwise. The expression "terminal cancer" is a poor one. A patient may be critically ill due to the effects of a cancer and improve at least temporarily or even permanently following appropriate therapy. Administration of an ineffective drug such as amygdalin instead of such appropriate therapy would deprive a significant number of patients of their chance for some relief, temporary though it might be in many cases.
>
> It is true that many patients come to a point in time when only supportive care is possible. It has been argued that administration of amygdalin to these patients would do no harm. No one knows whether or not the drug would do no harm. There

[30] Some examples of resort to laetrile by patients before resort to conventional therapy are in "Healing: A Doctor In Search of a Miracle", William A. Nolen, M.D. (Random House); Ad.R. 197, Donald C.S. Tan M.D. and the Report of the Alameda County Coroner on his investigation of a death by cyanide intoxication of a patient on laetrile therapy, Appendix B hereto at pp. 69-71.

The importance of early detection and treatment in terms of survival when cancer is localized as opposed to delay in treatment until the cancer has spread is set forth in the American Cancer Society's 1979 Cancer Facts and Figures at page 9. The chart shows the following five year survival rates for localized as compared to disseminated cancer: bladder 72/14; breast 85/47; colon-rectum 71/26; larynx 79/32; lung 33/4, oral 67/25, prostate 70/35, uterus-cervix 78/37 and uterus-corpus 86/33.

> is no reason to believe that it would do any good. And if it were made generally available for that group of patients it would inevitably be given to or obtained by others for whom effective therapy is available. Once the decision is made to permit the distribution of one useless drug for such cases there will certainly be more proponents demanding that the same loophole in the law be open to their unproven remedy.[31]

Further, approval of laetrile for the terminally ill would give the appearance of an official imprimatur, and would encourage use of the drug by patients who could be helped by legitimate therapy. See the Commissioner's Opinion at Petitioner's Appendix p. 268a. James Harvey Young, a noted medical historian, testified on the basis of his study of past unproven cures that "[p]ermitting laetrile's use in terminal cases gives it a credence among the public at large that will expand its use in early cases, for people will prefer taking a 'vitamin' to confronting the surgeon's knife." Petitioners' Appendix at 269a. Dr. Samuel G. Klagsbrun, a psychiatrist who works with cancer patients at St. Luke's Hospital in New York, testified that "[p]ermitting laetrile to be used by any population of cancer victims would have the correlative effect of creating the misimpression in the minds of other cancer victims that the drug is, in fact, safe and effective for a broader population." Petitioners' Appendix at 269a.

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[31] To the same effect see Ad.R. 191 at H6, the affidavit of Philip Schein, M.D.:

"If Laetrile is permitted in general clinical use without its effectiveness having first been demonstrated by substantial evidence, it will open a Pandora's box which will plague both the medical profession and the public for many years to come. The precedent would allow many other ineffective drugs to be used under the guise of effective placebo therapy or psychological support—in conditions for which there are not data to support their effectiveness."

The record of this proceeding makes highly visible the practical impossibility of restricting the importation of latetrile to the terminally ill. The obstacles to such restriction were attested to by an officer of the Drug Enforcement Administration one Kenneth Durrin, Acting Director of the Office of Compliance of the Drug Enforcement Administration. Mr. Durrin related the agency's experience in regulatory other controlled substances available for limited use, e.g., cocaine and then applied that experience to the Laetrile problem. He testified that since Laetrile does not appear to have a central nervous system effect, it would not come under the controlled substances act and the controls available under the Act. "Absent the kinds of controls available under the Controlled Substances Act—and indeed even with such controls—it is my opinion that a drug such as Laetrile could not effectively be restricted to a class of terminally ill cancer patients. For example, absent a quota on production, manufacturers would not be limited to producing an amount of Laetrile sufficient only to provide a source of supply for terminal cancer patients. Manufacturers would not be restricted in the channels in which they could permissably distribute the drug. They would not be required to report transactions in Laetrile." Ad.R. 435 at 7293.

The inability to restrict usage also flows from the practical impossibility of arriving at an objective standard that will not lend itself to abuse. See discussion at pp. 7-10, *supra.*

Both the potential for and actuality of abuse is apparent from the record before the court of appeals. Food and Drug Administration investigators telephoned patients who had executed patient importation affidavits in the district court proceeding. A common pattern emerged. The need of patients whose six month laetrile requirements were 26 ampoules and 180-185 tablets were

stated by affidavit without their permission to be 150 ampoules and 750 tablets. The excess is apparently used by the "importer" to supply patients who had not executed affidavits. See Ct.R. 409-414, 423-480 and see Ct.R. 1505 and attachments. This type of abuse resulted in a complaint for forfeiture before the district court in Maryland [32] to seize from a pharmacist acting as agent for patients holding laetrile import affidavits the laetrile procured by him which exceeding their actual orders:

> 4. As agent for the persons named in the affidavits, Mr. Henderson was authorized to deliver to these persons the amounts of Laetrile imported on their behalf and for their personal use.
>
> 5. Investigations by United States Food and Drug Administration investigators have revealed that the affidavits are fraudulent in that patients on whose behalf affidavits were presented to customs officials either ordered significantly less than the amount of Laetrile declared on the affidavits or did not order any Laetrile whatsoever and are unaware of any affidavit being executed on their behalf.
>
> 6. Food and Drug Administration investigations further reveal that Mr. Henderson has solicited abandonment of Laetrile from patients who ordered Laetrile and on whose behalf affidavits were presented to customs officials and that either as a result of such solicitations or for other reasons, some patients have cancelled or reduced their orders for Laetrile.
>
> 7. Food and Drug Administration investigations further reveal that affidavits presented to customs officials contain false information in that the amounts

[32] United States v. Articles of Drug . . . Amigdalina Cyto Pharma De Mexico, S.A., Docket No. K77-1283 filed on August 4, 1977. The complaint and Motion for Patient Release on Seized Goods and Supervised Delivery to Certain Patients are appended hereto as Appendix D.

> of Laetrile represented to have been ordered by the patients exceeds the amounts actually ordered and that Mr. Henderson uses these amounts of Laetrile not ordered by patients to create a stockpile from which he then sells to other persons who have not executed affidavits presented to Customs for purposes of facilitating importation of the drug for their use.

A final example of abuse arises in a case involving a minor treated with chemotherapy under court order whose parents were also administering laetrile and other therapies to him without court permission. During a hearing on whether the child was harmed by the addition of laetrile, massive doses of vitamin A and enzyme enemas, a doctor testifying for the parents stated that he did not believe that the minor was terminally ill but that he would execute an affidavit such as that required by the district court in the case before this Court stating that the minor was terminal in order to permit the child to procure a supply of laetrile.[33]

The dangers posed by approval of laetrile for the terminally ill are particularly clear in the case of children with cancer. Children constitute only one percent of the cancer cases in this country but cancer represents the most serious threat to childlife next to accidents. Childhood cancers are also the category in which the greatest success in long-term remission and "cures" have been made. Yet, the natural desire for parents to avoid the suffering for their child which is a part of conven-

[33] In Custody of a Minor (Appendix C), Dr. Ernesto Contreras testified that the minor does not have terminal cancer. He also testified that despite the fact that the minor does not have terminal cancer, he would be willing to sign a "Bohanon affidavit" attesting that Chad does have terminal cancer. On the following day, Dr. Bruce Halstead of California made the same statement.

The record in this case is sealed until an appeal is taken. The information in text was received from a physician-witness for the State of Massachusetts.

tional treatment makes this class a minority which requires protection from the loophole in the law advanced in the *Rutherford* court appeal.

This need is illustrated by a recent Massachusetts case arising from a physicians request to have a child committed to the Department of Public Welfare for the purpose of providing necessary medical care (chemotherapy) for the treatment of leukemia. *Custody of a Minor*, S.J.C. No. P-1422, Mass. Supreme Court, Plymouth Division of April 18, 1978 in Civil Action No. 78-6916.

Indeed, given the nebulous benefits which can be anticipated by the truly terminal patient from access to laetrile, the court of appeals exemption deprives that class of patient of very real and needed protections stemming from the nature of end-stage disease which are secured to this class by the federal drug laws. The court of appeals asked the question:

> [W]hat can "generally recognized" as "safe and effective mean to such persons who are so fatally stricken with a disease for which there is no known cure?[34] What meaning can "effective have in the absence of anything which may be used as a standard. Under this record Laetrile is as effective as anything else. What can "effective mean if the person, by all prevailing standards, and under the

[34] This finding flies in the fact of administrative and court interpretation which has hitherto consistently found the Act and its safety and effectiveness provisions applicable to cancer patients. See e.g., Hearings on S. 1552 Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary 87th Cong., 1st Sess. Part 5, at 2588 at which the Secretary of HEW explained the FDA's attitude as follows: "If the drug is offered for the treatment of progressive or life threatening diseases such as cancer, or if the drug is seriously toxic or has alarming side effects we now consider its effectiveness." (emphasis added). See also, Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), cert. denied, 414 U.S. 944, and the decision at pp. 15-18, *supra*.

> position of the Commission takes, is going to die of cancer regardless of what may be done. (Petitioner Appendix at 6a).[35]

The Court of Appeal's focus is apparently restricted to "cure" and is thus too narrow in terms of the class it addresses,—the terminally ill. Bernard C. Meyer in an article "Truth and the Physician" reprinted in Ethical Issues in Death and Dying (1977) at 533, observes that the "Physician's response once he can no longer arrest disease is to assuage discomfort and distress". A cure may not be possible, but other relief for the terminally ill may be, for example, pain control, appetite stimulation, tranquilization.

In the Laetrile Hearings it became clear that the purveyors of laetrile have moderated their claims for the substance in recent years. For the most part, it is no longer openly claimed[36] that laetrile cures cancer [although this is the expectation of the cancer victims that turn to it].[37] The current thrust of the laetrile

[35] There is inconsistency in the Court of Appeals finding that the terminally ill are excluded for the strictures of the Act while at the same time confining the utilization of laetrile to an injection route.

[36] Compare the remarks of Lewis Thomas, M.D., Director of the Memorial Sloan-Kettering Cancer Center at Laetrile Hearings pp. 13-14 ("It is no longer openly claimed that Laetrile cures cancer", although some of the leaflets and public releases hing broadly in this direction.") with the remarks of Senator Kennedy at p. 257: ". . . the thing that's interesting about your careful choice of words about the impact of this [Laetrile] would be you had no reluctance of using the word 'cures' or 'recoveries' in the transcripts here before the California case. It was a tape of the town meeting. And I'll just read: 'Some cases have undergone clinical arrests, or for other practical purposes, we might describe as cures or recoveries.' "

[37] See Record Volume XIV, Transcript on Plaintiffs Motion For Temporary Injunctive, July, 1975, Ct.Tr. 6 ("Laetrile . . . has completely neutralized his . . . cancer"); 7. ("cancer victors' . . . have been denied what many, many physicians and high level biochemists feel is a complete cancer remedy. Nothing is complete, but I

proponents seems to be that it will dramatically relieve pain, improve appetite, promote weight gain, reduce the odor associated with cancer, improve the cancer patients general sense of well-being, control or prevent cancer.[38]

The terminally ill are entitled under the Act to the assurance that the products they seek to use are effective not only for cure or treatment but also for these other purposes.

Cancer victims constitute a minority group in our society; terminal cancer patients constitute an even smaller minority, but like other groups, they have a right not to be exploited. In the case of cancer drugs, particularly the exercise of government power of protection, premarket clearance is not only reasonable, but necessary to protect the compelling public interest in effective cancer therapy, and in assuring that non-therapeutic drugs do what they say. In view of the widespread incidence of cancer, the serious consequences of the disease, the expe-

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mean a very effective remedy); 30 ("I am alive because of it"). 86 ("I hope and pray that we will get his protective order to keep him alive.")

[38] See e.g., Laetrile Hearings at pp. 13-14 (Dr. Thomas). 246-247, 271-72 (prevention, control, pain relief, appetite increase, weight gain, feeling of well-being), J.A. Richardson, M.D. physician using laetrile, 295-297 (stimulation of appetite, weight gain, decrease or eliminate pain, bad odor, pallor, remarks of Robert Bradford, Committee on Free Choice for Cancer Treatment. Mr. Bradford also stated at p. 295 that "Laetrile is not offered as a cancer cure. There is no cure for cancer . . . In the very best of instances it may effect a control—but not a cure—of cancer . . . ."). See also the opinion of the Commissioner of the FDA at Petitioners Appendix pp. 73a-78a.

Compare the Alameda County Coroner's Report, Appendix B hereto at 17a in which a patient with advanced carcinoma of the breast who was on laetrile treatments. The medical report furnished to the Coroner from the laetrile clinic at which she was treated since March of 1978 referred to her complaints of "loss of sleep associated with severe pain." She died of cyanide intoxication in December of 1978.

rience with the particular vulnerability of cancer patients and their families to promoters of easy money-making schemes labeled in mysterious scientific dress, it is imperative that the standards of consumer protection set forth in the federal drug acts be maintained.

Further, the Court of Appeals assumes that Laetrile by injection is safe.[39] This assumption is unsupported by the record before this Court. An awareness of the actual and potential toxicity of Laetrile has emerged in recent expressions of scientific opinion.[40] Of particular significance is the article "Laetrile Toxicity: A Report of Two Cases", Smith and Schein, 238 Journal of the American Medical Ass'n 1361 (Sept. 1977). This article describes a case of serious side effects relating to administration of laetrile by injection and the cessation of such side effects when the laetrile was withdrawn.

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[39] The Court of Appeals direction to the FDA to promulgate regulations relating to the use of laetrile by injection by the terminally ill, cannot be executed. The laetrile proponents have been unable to provide a consistent picture of what the components of laetrile are. The samples alleged to be laetrile seized and analyzed by the FDA have had differing chemical compositions. Specifically, Commissioner Kennedy testified at pp. 4-5 of the Laetrile Hearings that the substance "has no fixed identity in the hands of our analytical chemists who find that the amount of amygdalin and the ratio of its isometric forms varies widely in the samples of materials we had seized." See also the Commissioners Opinion at Petitioners Appendix pp. 182a-187a.

Compare, Durovic v. Richardson, 479 F.2d 242, 251 (7th Cir. 1973), cert. denied, 414 U.S. 944. In that case, the Court of Appeals, as one rationale for its decision that Krebiozen could not be generally recognized as safe even in the narrow sense of non-toxic by qualified experts found that as of "October 9, 1962, the identity and composition of Krebiozen was completely unknown."

[40] See e.g., Jukes "Laetrile for Cancer" 236 Journal of the American Medical Ass'n 1284 (1976); Hambert, "Fatal Cyanide Poisoning: Accidental Ingestion of Amygdalin," 238 Journal of the American Medical Ass'n 482 (1977) and Lewis, "Laetrile" 127 Western Journal of Medicine 55 (1977); and the toxicity issue is discussed at pp. 59-71, *infra*.

II. APPLICATION OF THE APPROPRIATE BURDEN OF PROOF AND REVIEW CRITERIA DEMONSTRATES THE DISTRICT COURT'S ERROR IN FINDING AN EXEMPTION FOR LAETRILE UNDER THE 1962 GRANDFATHER CLAUSE FROM THE SAFETY AND EFFICACY REQUIREMENTS OF THE FEDERAL DRUG LAWS AND SUPPORTS THE COMMISSIONER'S FINDING THAT NO EXEMPTION IS WARRANTED

A. Standards of Proof and Review Criteria

No matter how a drug becomes the subject of an FDA rulemaking proceeding—agency initiative, manufacturer or other drug proponent initiative, court referral—the burdens of proof and proceeding and the standards of review established by the federal drug laws as construed by the courts are the same. The statute and regulations do not require the Food and Drug Administration to prove a drug ineffective but rather, the burden of proceeding and proof of safety/efficacy by a substantial amount of well documented evidence lies with the proponents of the drug.[41] The court of appeals and the district court below, from the outset, have eschewed the statutory standard and have created a hybrid standard. The standard literally requires the FDA to initiate an administrative proceeding on drug status and bear the burden of proof in that proceeding whenever, in the absence of an administrative record or new drug application, the FDA proceeds with the presumption of "new drug" status. As stated by the Court of Appeals:

> We are unable, however, to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is. . . To support its determination the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as "safe and effective," and that Laetrile is not grandfathered by either of the exemptions discussed above.[42]

[41] *See e.g.* Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609, 617 (1973); Ubiotica Corp. v. FDA, 427 F.2d 376, 378 (6th Cir. 1970); Upjohn Co. v. Finch, 422 F.2d 944, 955 (6th Cir. 1970); North American Pharmacal, Inc. v. HEW, 491 F.2d 546, 550-51 (8th Cir. 1973).

The FDA is not required by any provision in the federal drug laws or any principle of administrative law to initiate a rulemaking proceeding to determine the "new drug" or "grandfather" status of a product before the agency can declare that product to be a "new drug." 42 Federal Register 10067 (1977). For example, the predicate of each enforcement action which the agency brings to prevent and punish violations of 21 U.S.C. §§ 331(d) and 355(a) is the "new drug" status of the product involved. The decision made to initiate enforcement proceedings is technically based on probable cause that a drug is in violation of the Act.[43] The absence of an "approval" or "exemption" in its records that the FDA can point to requires a "new drug" description until the proponents of the drug have proven differently.

A reversal of burdens of proof and proceeding when an affected patient requests relief conflicts with the decisions in other courts. For example, District Court Judge Chapman in *Julian H. Morgan Sr., et al.* v. *David Matthews, et al.*,[44] denied the same relief request by the patient plaintiffs in *Rutherford* with the following rationale:

> Plaintiffs apparently contend that the burden is on the FDA to approve or disapprove of a new

[42] 542 F.2d at 1143 and Petitioners Appendix at 32, 13a nn.3-4, 14a n.5.

[43] *See* Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950).

[44] Appendix A hereto.

drug in the first instance, since they complain that the FDA "has failed, without adequate explanation, to approve Laetrile for distribution and use in the United States. . . "The language and history of the Act demonstrate that it is not the responsibility of the FDA to initiate applications on its own in the absence of an application that conforms with the statutory requirements of § 505(a) and (b). No such application has been filed here. See Finding of Fact 2, *supra.*

The FDA has been given the responsibility of "approving applications". Therefore, it is apparent that they must be submitted for approval. This conclusion conforms with the Act's legislative history.

The House Committee Report discussion § 505 during its initial drafting in 1938 stated that

> This provision will not put the Federal Government into the business of developing new drugs, nor will it require the Governement to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market.

H.R. Rep. No. 2139, 75th Cong., 3rd Sess. (April 14, 1938), p.9. Further discussion was held as to this section in the House Report of 1962 amended version, which indicates that application was to be made by the manufacturer:

> Section 505 of the Food, Drug and Cosmetic Act prohibits interstate shipment of a "new drug" . . . unless it is first cleared for safety through the filing of a new drug application by the manufacturer.

> H.R. Rep. No. 2464, 87th Cong., 2d Sess. (Sept. 22, 1962), p.3 [45]

Further, Judge Kiley, in *Tutoki* v. *Celebrezze*, 375 F.2d 105 (7th Cir. 1967) denying declaratory relief against the FDA to cancer patients seeking Krebiozen because of their failure to exhaust administrative remedies, expressly found that the statute did not preclude cancer patients from sponsoring an NDA for Krebiozen. Finally, Judge Hastings speaking for a unanimous court in *Rutherford* v. *American Medical Ass'n et al.*, 379 F.2d 641 (7th Cir. 1967), found as one basis for his decision that the FDA need not cease its interference with patient/physician procurement of Krebiozen, that the Krebiozen proponents had not shown that they had made a good-faith attempt to comply with the procedures established by Congress for the introduction of new drugs. The court reasoned as follows:

> In their complaint, plaintiffs have alleged, in effect, that the FDA has systematically attempted to discredit Krebiozen and to prevent its introduction into commerce. It is argued that on a motion to dismiss, we must accept the truth of these allegations.
>
> Accepting their truth arguendo, plaintiffs still have not shown that they have in good faith attempted to comply with the procedures established by Congress for the introduction of new drugs, nor has it been shown that the failure to apply can be attributed solely to the activities of the FDA and the defendants. The fact that compliance might be expensive and burdensome, is not unfairness in the procedure, but a consequence of a reasonable Congressional scheme for the introduction of new drugs.
>
> Without an attempted good faith application for approval or exemption, we have no jurisdiction to de-

[45] *Id.* at page 5.

> termine whether the FDA has illegally placed impossible or unreasonable conditions on approval or exemption, or has made requests for information impossible to fulfill, or whether the FDA has been dilatory, biased, or discriminatory. Until someone has attempted to comply with the Act with respect to Krebiozen, plaintiffs' appeal should be to the sponsors of the drug.[46]

Thus in parallel cases, courts have held that the shift of proponent position from manufacturer/developer to patient permitted no dilution of the standards and procedures for determination of the status of the drug.

Deviation from the prescribed statutory standard of proof is also inconsistent with the relative positions of the parties in this proceeding. The "evidence" which the FDA is supposed to provide lies within the control of those physicians and manufacturers who are said to be using and making Laetrile. This is not an enforcement proceeding in which the Government by seizure/subpoena or other process can "require" the production of evidence. The record in the Laetrile Rulemaking proceeding is clear that the proponent manufacturer/developers of the drug have not made a good faith attempt to comply with the NDA or IND procedures. They submitted applications in 1962 and 1970 but when notified of deficiencies did not come forward with submissions conforming with statutory and regulatory criteria to correct those deficiencies.

No attempt was made by the proponent manufacturers/developers in the rulemaking proceeding to utilize this opportunity to come forward with the quantity and quality of proof to support approval of a "new drug." One conclusion that may be drawn from this factual scenario is that the manufacturer/developers of Laetrile

[46] 379 F.2d at 643.

are utilizing the cancer patient as a pawn to effect an end run around the provisions of the provisions of the federal drug laws.

The statute and case law both sustain the proposition that the burden of proceeding and providing evidence that will sustain the substantial evidence tests imposed by the federal drug laws for the admission of a "new drug" to interstate commerce, lies with the Laetrile proponents. The only issue involved in the decisions below which concerns the presence or absence of such substantial evidence [47] is the district court's finding that the 1962 grandfather clause is applicable. This presents an alternative ground for or reversal or affirmance of the court of appeals decision by this Court.[48] Entitlement to the grandfather exemption of the 1962 amendments, i.e. Section 107(c)(4) of the Food and Drug Act,[49] is limited to drugs which:

1. feature *today* the identical chemical composition recommended dosages, and claims made in labeling as existed on October 9, 1962, *and*
2. were used or sold commercially in the United States on October 9, 1962, *and*
3. were generally recognized by the experts as safe; *and*

[47] See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 632 (1973).

[48] The district court apparently concedes Laetrile's status as "drug" (Petitioners Appendix at 18a) and its inability to meet the "efficacy" standards of the Act (Pet. App. at 22a), thus the "exemption" of laetrile from new drug status by application of the 1962 grandfather clause (Pet. App. 25a) is the alternative grounds for affirmance which involves the scrutiny of the record and allocation of burden of proof.

[49] Pub. L. 87-781, found as a note to 21 U.S.C. § 321. Section 107(c)(4) is quoted in full in the statutory appendix hereto.

4. were not covered by an effective drug application.[50]

The grandfather clause exception to the federal drug laws is construed strictly against those invoking it.[51] The failure of a drug to meet just one of these criteria extinguishes altogether its entitlement to grandfather status. The record in this proceeding clearly demonstrates that laetrile fails to meet each and every one of the four criteria.

The remanding opinions and orders recognized the "primary jurisdiction" of the FDA to determine the "status" of a drug and directed that the determination be made via a rulemaking proceeding.[52] The FDA acted. The resulting Commissioner's decision is subject to the standards of the court scrutiny applicable to review of agency action. The review court is required to view the record as a whole[53] and determine whether the Commissioner has articulated the grounds of his decision, whether those grounds are consistent with the statute, and whether

[50] United States v. Allan Drug Corp., 357 F.2d 713, 718-19 (10th Cir. 1966), *cert. denied*, 385 U.S. 899; United States v. 1,048,000 Capsules, More or Less, 347 F. Supp. 768 (S.D. Tex. 1972); see also Rutherford v. United States, 542 F.2d 1137, 1141 (10th Cir. 1976). The Commissioner concedes issue No. 4 in the Notice of Rulemaking and it need not be addressed here.

[51] See e.g., United States v. Allan Drug Corp., 357 F.2d 713, 718 (10th Cir. 1966), cert. denied, 385 U.S. 899 (1966). Accord Durovic v. Richardson, 479 F.2d 242, 250 n.6 (7th Cir. 1973), cert. denied, 414 U.S. 944; United States v. An Article of Drug . . . Bentex Ulcerine . . . , 469 F.2d 875, 878 (5th Cir. 1972), cert. denied, 421 U.S. 938 (1973); United States v. 1,048,000 Capsules, More or Less, et al., 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff'd 494 F.2d 1158 (5th Cir. 1974).

[52] Rutherford v. United States, 542 F.2d at 1143-1144 and Pet. App. at 12a.

[53] See the Administrative Procedure Act 5 U.S.C. Section 706, and see Diamond King Ranch, Inc. v. Morton, 531 F.2d 1397, 1405 (10th Cir. 1976).

those grounds are supported by the evidence of record. In short, if the Commissioners decision shows that the FDA has a reasonable basis for concluding that the drug proponents submissions did not comply with the substantial evidence requirements of the statute and regulations; the Commissioner's decision should be affirmed.[54] As the 10th Circuit itself has indicated:

> Review under this provision of the A.P.A. provokes injury whether the administrative decisions were based on a consideration of all the relevant factors and whether there was a clear error of judgment. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L. Ed2d 136. Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency. Id. The court's function is exhausted where a rational basis is found for the agency action taken. Udall v. Washington, Virginia and Maryland Coach Co., 130 U.S. App. D.C. 171, 398 F.2d 765, 769, cert. denied. Washington Metropolitan Area Transit Com. v. United States, 393 U.S. 1017, 89 S.Ct. 620, 21 L.Ed2d 561.

Application of the proper standard of proof and review criteria supports the conclusion reached by the Commissioner, detailed below, that the drug Laetrile does not satisfy any of the elements of the 1962 grandfather clause.

[54] Sabin v. Butz, 515 F.2d 1061, 1067 (10th Cir. 1975).

B. Laetrile Is Not Entitled To Grandfather Status Because Its Chemical Composition And Recommended Conditions For Use And Administration Are Not The Same Today As They Were On October 9, 1961 [55]

1. *The Relationship Between Laetrile and Amygdalin*

Laetrile is the term used to describe a class of cyanogenic glucosides of which the substance amygdalin is the primary ingredient.[56] The terms amygdalin and Laetrile are often used interchangeably. This stems from the fact that amygdalin is the one ingredient which in varying percentages has been consistently present in the "laetriles." However, this interchangeable use is incorrect.[57] Laetrile and amygdalin differ in formulae and

[55] The variations in composition and conditions of usage for the drug Laetrile are set forth graphically in the time line flow chart at pp. 65-68 of this brief. The chart by years from 1920's through 1978 represents the claims made by Laetrile's mechanism (rational) of drug action, label/pamphlet claims, formulation, method of preparation (reconstitution), dosage, route (method of) administration, use as an investigational drug which is inconsistent with claims of commercial marketing and the representations as to safety and toxicity made Laetrile labels and pamphlets.

[56] See Dorr, Paxinos "The Current Status of Laetrile," 89 Annals of Internal Medicine 389 (1978) (hereinafter "Annals"). See also, Korbitz, Ad.R. 181 at 195E, "Laetrile is a somewhat crude preparation of amygdalin."

[57] See e.g., Annals supra at 389. See also Harold W. Manner, Ph.D., at R262 and W. Sherwood Lawrence, M.D., at Ad.R. 183 at p. 7; Opinion of the Attorney General of Illinois "Public Health: Interpretation of Act Allowing Giving of Amygdalin or 'Laetrile' to Terminal Cancer Patients, File No. S-1331, January 15, 1978 ("Amygdalin" and "Laetrile" (illegible) separated and interchangeably in the statute; amygdalin has an accepted scientific chemical formula and "Laetrile does not; The statute intends "Laetrile" as covered by the statute "when its active ingredient is amygdalin."); See also Markle, Peterson & Wagenfeld, "Notes From the Cancer Underground: Participation in the Laetrile Movement" 12 Social Science & Medicine 31, 37n (1978) (There is some doubt

also in chemical structures.[58] "Under British patent 788,855 (1958) Laetrile is described as 1-mandelo nitrile-beta-glucuronic acid and differs from amygadlin by the absence of the second glucose moiety present in tandem in the readily available amygdalin." The Commissioner in his rulemaking decision correctly recognized the distinctions between the substances. See Pet. App. at 58a-70a.[59]

2. *The Record On The Chemical Composition And Conditions Of Use For Laetrile*

The record in the rulemaking proceeding fully supports the Commissioners determination that Laetrile is not a compound which has enjoyed any continuity of composition or recommended conditions of use and administration. See Pet. App. at 58a-73a, 182a-204a. By way of contrast, the district court (Pet. App. at 25a-34a) exempts Laetrile by application of the 1962 grandfather clause, but does not address any of the issues in-

that Laetrile and amygdalin are, in fact identical substances). Ct.R. 1507 "Amygdalin (Laetrile) Therapy, 1977, Bruce Halstead, M.D. This booklet was plaintiffs exhibit before the district court. At page 3 of the booklet, Dr. Halstead, a laetrile advocate, states: "The terms amygdalin and Laetrile are frequently used interchangeably by laymen, but are not chemically synonymous."

[58] See Annals at 390; Fenselau "Mandelonitrile B-Glucuronide: Synthesis And Characterization, 198 Science 625, 626 (1977); Pet. App. 60a-64a and Ct.R. 1507 supra note at pp. 4-5. The amygdalin chemical formula is expressed as d-mandelonitrile-B-D-glucoside-6-B-D glucose and its structure is represented as $C_{20}H_{27}NO_{11}$. The Laetrile chemical is usually expressed as laveo-mandelonitrile-B-glucuronic acide or $C_{14}H_{15}NO_7$.

[59] The significance of the distinctions between Laetrile and amygdalin arises from the arguments made by the laetrile proponents below and echoed by the district court (Pet. App. at p. 26a-34a) that if Laetrile and amygdalin are interchangeable, amygdalin availability as a chemical from drug supply houses satisfies the commercial marketing requirements of the 1962 grandfather clause. The fallacy of this argument is discussed in text at pp. 54-56, *infra.*

herent in the labeling/conditions of use arm of the grandfather provision: Drug formulation, consistency, dosage, route of administration, theory of action and claims for the product now and prior to October 9, 1962.[60] With one exception,[61] the only reference to chemical formula made by the district court relates to amygdalin (Pet. App. at 34a n.24) not laetrile. See discussion on interchangeable use at pp. 42-43, *supra*.[62]

Table A at pp. 65-68, infra, demonstrates the lack of consistency and predictability as to method of action, chemical formula, dosage, route of administration, claims for use as well as safety and toxicity and the absence of commercial marketing data in the record. This is the

[60] Since all grandfather criteria must be met before an exemption is applicable, this deficiency alone nullifies the district court's finding of an exemption. See note 51 *supra*, and United States v. Bentex Ulcerine, 469 F.2d at 878.

[61] The district court's sole reference to Laetrile's formula is at note 17 at Pet. App. 26a. The district court attempts to explain away the obvious differences between a specific laetrile and amygdalin formula by referring to R.183 at which Mr. Krebs stated that he had abandoned that specific synthesis of laetrile because it was too expensive to formulate. The district court makes no attempt to explain the many other differences in laetrile versus amygdalin formulae. See e.g. Ad.R. 183, Attch. 16 at pp. 27-28 (Laetrile= Sodium 1-mandelonitrile-beta-glucuronoside); Ad.R. 167 Exh. 2 at p. 143 (Laetrile=1-mandelonitrile-beta-glucoroniside); and see the discussion in text and notes at pp. 42-43, *supra*. The articles in Science and the Annals of Internal Medicine diagram laetrile/amygdalin and show the differences in chemical formula.

[62] The district court attempts to dilute the effectiveness of the grandfaster clause by construing it as exempting any drug "to the extent that it is currently being used for the same purposes and under the same conditions and labeling as on October 9, 1962." (Pet. App. at pp. 15a-16a, note 7). This construction flies in the face of United States v. Allan Drug Corp., 357 F.2d 713, 718 (10th Cir. 1966) cert. denied, 385 U.S. 899. In that case, the court held that a drug relabeled by court order after 1962 to eliminate false claims was not entitled to a grandfather clause exemption. The Allan court "confine(d) the exemption to drugs intended solely for use under the conditions prescribed on the effective date of the Act" 357 F.2d at 719.

bedrock underlying the Comissioners decision that the elements of a grandfather exemption have not been supported by substantial evidence. The Table also demonstrates the error of the district court. By way of illustration, some of the inconsistencies in chemical composition and usage of the drug set forth in the Table are discussed below.

Laetrile traces its genesis to the work of Dr. E. T. Krebs, Sr. with amygdalin in the 1920's,[63] but its evolution since that time has changed its chemical composition materially. Dr. Krebs himself admits that the name was not coined until 1949, and that the name has been used since that time for the final form of the amygdalin produced by Krebs, regardless of its actual chemical composition.[64]

The degree of change in the composition of Krebs' amygdalin, or laetrile, over the years and the precise dates on which changes were effected, are difficult to pinpoint due to the general lack of knowledge and information on the product.

Almost without exception, the specific evidence contained in the record as to labels, clinical formulae, pamphlets relating to usage and the like do not come from the proponents of the drug who present conclusions without supporting data. Specific evidence comes from those testifying against the safety/efficacy/general recognition of laetrile who cite specific materials distributed by the laetrile proponents in support of their claims.[65]

[63] Ad.R. 184 (Affidavit of Carl M. Leventhal, M.D.) Exh. 6.

[64] Id.

[65] Ad.R. 434 (Affidavit of Carl M. Leventhal, M.D.) at M 280. "The testimony by laetrile proponents on use prior to October 10, 1962 do not provide information on the composition of the drug, form, strength, purity, recommended conditions of use, route and method of administration, dosage schedule."

Just as the chemical composition of laetrile has been in a state of evolution over the years, so too has its labeling with respect to the dosage to be administered and the purpose of the drug. For example, the shipment of laetrile to Dr. Cooper in 1952, which clearly was for investigational purposes,[66] was accompanied by a letter which addressed dosage as follows:

> In these early days *it is difficult to be too specific about a good many things*, but the consensus of opinion at the moment is that the following dosage schedule is best:
>
> For the rapid or high-grade malignancies 50mg. every other day;
>
> For the slow or low-grade malignancies 50 to 100 mg. every five or seven days;
>
> For the usual or intermediate case 50 mg. every three to five days.[67]
>
> [Emphasis added.]

In fact, in the early 1950's uncertainty about the use of laetrile was such that in some respects Spicer-Gerhart, a manufacturer of laetrile, refrained from advising the method of use:

> The injection usually is given intramuscularly although when it is possible to give it directly into the malignant lesion, this may be done with advantage. *However, perhaps one had better leave directions of that sort for a little later*, after you have had some personal experience with the substance.[68]

On one point, Spicer-Gerhart was quite firm: laetrile was *not* to be taken orally. According to a mimeograph prepared by the Company for guidance to doctors on the

[66] Ad.R. 388, Exh. 2, 3 (Affidavit of John R. Cooper, M.D.).

[67] *Id.*

[68] *Id.*, Exh. 4 (emphasis added).

use of laetrile, the substance was described as "extremely toxic by [oral] route of administration." [69]

In 1952 Spicer-Gerhart described the theory behind laetrile as follows:

> In order that there shall be no misunderstanding, may I remind you that, according to the theory outlined, Laetrile has a destructive effect only. Certainly, this destructive effect is very definite and sometines very quick, but it does have to be borne in mind that Laetrile makes no contribution whatever toward the remainder of the patient's problem—reconstruction and repair. From the very nature of the action of Laetrile, it will be obvious that under certain circumstances, hemorrhage might take place and mechanical problems involving the disposal of neurotic breakdown problems might arise.[70]

In a later pamphlet by Dr. Krebs, Sr., the following statements were made with respect to laetrile:

> Laetrile does not palliate, it acts chemically to kill the cancer cell selectively without injury to the normay tissues of the body.
>
> The usual daily dose of Laetrile is 10 mg. of the glucoside amygdalin for every pound of the patient's weight. Some patients may need 15 or even 20 mgs. but rarely more except in cases of pancreatitis enzymes insufficiency due to inhibitation. . .
>
> Laetrile is dissolved in sterile distilled water using 4 to 5 cc for every 1000 mgs. of Laetrile.
>
> The injections should be given intravenously every day until . . .
>
> They are not only important food for nutrition they also act as a vitamin to supply the body with the CN

[69] *Id.*, Exh. 5.

[70] *Id.*, Exh. 2.

group for the biosynthesis of another vitamin cyanocobalamine.[71]

The record abounds with other examples of labeling changes with respect to laetrile. For instance, the affidavit and supporting exhibits submitted by Robert S. K. Young, Ph.D., compared the labeling and other information contained in the New Drug Application for laetrile (NDA 14-032) received by the FDA during an establishment inspection of Krebs Laboratories on April 23, 1965. Dr. Young identified some of the significant labeling differences as follows:

(a) The formulation of the drug had been changed. In 1962, the formulation contained N, N diisopropylammonium iodide and saccharides in addition to amygdalin and these materials were to be reconstituted with an isotonic solution. In 1965, the formulation contained only amygdalin and this material was to be reconstituted with water, which is not isotonic.

(b) The class of patients for whom the drug is recommended had been changed. In 1962, the label characterizes the drug as a palliative agent for use in "cancers beyond aid by standard agents," and warns that "*It is not to be employed to the exclusion of surgery, radiation or similar standard modalities so long as they are indicated.*" The 1965 labeling states that "Laetrile does not appliate, it acts chemically to kill the cancer cell selectively without injury to the normal tissues of the body." It goes on to warn that "The physician who is using laetrile to palliate his patients is not doing justice to his patient."

(c) The interaction of Laetrile with other forms of cancer treatment had been changed. In 1962, the

[71] Ad.R. (Affidavit of Robert S.K. Young, M.D., Exhibit C) which includes labeling obtained during an April 23, 1965 inspection of the Krebs Laboratories in San Francisco.

label states Laetrile "has no known therapeutic incompatibilities." It goes on to warn that "the general enhancement of the clinical condition of the patient is not to be considered as justification for the exclusion of standard modalities so long as they are applicable." In the 1965 material, the directions state that "The less drugs and medicines given, during the Laetrile treatment, the better. What should be especially avoided is . . . other cancer therapies, strong drugs . . . etc."

(d) The recommended route of administration had changed. In the 1962 labeling, "intravenous administration is preferred." The 1965 labeling advises that "Whenever it's possible to administer Laetrile by injection into the artery supplying the involved area this administration should be used." Specifically, injection into the external carotid or its branches, abdominal aorta, or internal iliac arteries is recommended. The 1965 labeling also recommends injection into the vault of the vagina and scrotal sac, and rectal enemas. I am generally familiar with the literature and reports relating to Laetrile and am aware that since 1965, there has been commercial distribution of dosage forms of Laetrile including tablets containing amygdalin, capsules of ground defatted apricot kernels, and a milkshake mix containing amygdalin all intended for oral use.

(e) The claimed mechanism of action of the drug had changed. In the 1962 material, the "Beardian thesis" was discussed as a theory. The 1962 labeling made no claim that Laetrile is a vitamin or provitamin, or that cancer is a deficiency disease. The 1965 labeling states that "Cancer is a deficiency disease" and there is a presentation of what role amydalin plays in the therapy of cancer in light of cancer of deficiency disease.

11. All of the above changes are medically important or have medically important implications that must

be reviewed scientifically. In the same order as I have reviewed them in 10, they are:

a. Formulation changes may reflect changes in the drug substance, and always reflect changes in the material to be administered.

Whenever the material to be administered is changed, it is important that the new material be essentially identical to the old material in strength, quality and purity.

b. The 1962 labeling restricts the use of Laetrile to those patients who all have conventional therapy, and prescribes use for the purpose of palliation of their disease. The 1965 labeling states that this drug should be used to mitigate the effects of the disease and implies that the drug is of curative value. Since Laetrile has no demonstrable effect on cancer, to use Laetrile in lieu of conventional therapy is to condemn to certain death those patients with curable forms of cancer, and to prolong the pain and suffering of those patients with treatable forms of cancer.

c. The 1962 mailing label warns that the conventional therapy not be withheld during Laetrile administration. The 1965 labeling suggest conventional therapy. Again, since Laetrile has no demonstrable effect on cancer, to use Laetrile in lieu of conventional therapy is to condemn to certain death those patients with curable forms of cancer and to prolong the pain and suffering of those patients with treatable forms of cancer.

d. Changes in the route of administration of a drug must always be scientifically validated. A drug may not be effective or may be more toxic when given by different routes of administration. The recommendation in 1965 that the drug be given by intra-arterial injection is particularly hazardous. These high pressure blood vessels

are difficult to enter successfully and are prone to continued bleeding after entry with a needle.

e. The claimed mechanism of action strongly suggest that Laetrile has a rational basis as a cancer therapy. Since it has no demonstrable value as a cancer therapy, to suggest that it has may influence some to use it who might not otherwise use it.[72]

Dr. Young's conclusion regarding "the numerous changes which have occurred in the composition, labeling, routes of administration, dosage form, intended uses and identity" of laetrile between 1962 and 1965 [73] in and of itself precludes laetrile from entitlement to the grandfather exemption contained in Section 107(c)(4).[74]

Ernest Krebs, Jr. at the hearings in Missouri stated that the dosage recommended for amygdalin has grown from 50 milligrams in 1932 to 17,000 milligrams today.[75] The book "World Without Cancer" discredits the 1953 California report of the analysis of patients treated with laetrile on the basis that the dosage given them was too low, only one fifteenth of the dose used now.[76]

Dr. Carl Leventhal sets forth an apt illustration of the importance of consistency in drug formulation and content:

Production of drugs may in a rough sense be analogized to baking a cake. Two cooks may start with identical ingredients, but the results of their labors may have different characteristics even if the same

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[72] Ad.R. 201 (Affidavit of Robert S.K. Young, Ph.D.) at 2.

[73] *Id.* at 2.

[74] Pub. L. 87-781, reprinted at 21 U.S.C.A. § 321 note and in Appendix B hereto.

[75] Ad.Tr. 238 (Testimony of Ernest Krebs, Jr.).

[76] Tr. 333.

recipe is used. In the case of drugs, slight and frequently unnoticed deviations in processing result in the production of essentially different drugs. This is particularly true in the case of amygdalin, since, during the manufacturing process, if ground, moist kernels are, prior to dilution, allowed to stand for a period of time, such as overnight, any amygdalin presented in the material can be transformed into cyanide, benzaldehyde, and sugar by enzymatic action. In such an instance there would be a diminished amount of or no amygdalin in the finished product."

Ad.R. 434 at M 279

It is manifest that both the composition of laetrile and the manufacturer's claims with respect to its use have changed dramatically over the years. Accordingly, laetrile does not meet the continuity-of-labeling requirements of the 1962 grandfather exemption and thus is not excused from the "new drug" requirement of the Food and Drug Act.

3. *Laetrile Is Not Entitled To Grandfather Status Because It Was Not Used or Sold Commercially Within the United States Prior to October 9, 1962*

Although the record contains evidence of use by physicians and others of a substance called laetrile prior to October 10, 1962, this limited use fails to constitute commercial use or sale as required by the grandfather provisions of the 1962 amendments. The requirements of commercial use or sale within the United States set forth in qualification (A) of the 1962 grandfather clause [77] means that the item must have been openly and readily available in the ordinary course of business as well as

[77] Section 107(c)(4), Pub. L. 87-781, *reprinted* at 21 U.S.C. § 321 noted in the statutory appendix.

free of all restrictions placed on investigational use.[78] Laetrile fails to meet either of these criteria.

First, laetrile certainly has not been openly and readily available in the ordinary course of business. The only record evidence of laetrile's marketing concerns limited and isolated manufacturing and distribution in the United States and some use outside of the United States. Use outside of the United States is not relevant to the grandfather exemptions in that the law specifically limits applicability to substances sold in the United States. Second, laetrile sales that did take place within the United States were neither widespread nor unqualified.

According to the developer of laetrile, the use of the drug in the U.S. was clearly for investigational purposes only. In an affidavit executed by Dr. Krebs, Sr. in 1965 he claimed:

> 7. As early as 1926 and up through 1962, I first began to ship and have done so continuously thereafter the Scarcarcinase extract (cf2), first the amygdalin (cf3), then the purified amygdalin (cf4), then the purified and lyophilized amygdalin (5), and then since 1949 (cf6) the latter under the name *Laetrile* to persons in other States outside of the State of California and in many other countries. *The above shipments were for investigational use only.*[79]

In fact, the record demonstrates that the manufacturers of laetrile held it forth for investigational use only as late as 1970. In 1962, an application for a new drug application (NDA) was submitted to the FDA for its consideration and in 1970 an application of an In-

[78] Durovic v. Richardson, 479 F.2d 242, 247-48 (7th Cir. 1973), *cert. denied*, 414 U.S. 944.

[79] Ad.R. 183 (Affidavit of W. Sherwood Lawrence, M.D.), Attach. 6, at 2 (emphasis added).

vestigational New Drug (IND) also was submitted.[80] These actions are significant because it has been judicially recognized that the presentation of an IND or NDA to the FDA implies that on those dates the drug involved was a "new drug"; otherwise the NDA or IND would not be required.[81]

Thus, the proponents of laetrile by their own actions have characterized laetrile as "new" and "investigational," and hence not "commercial" within the meaning of the 1962 transitional provisions. Consequently, laetrile is not entitled to a grandfather exemption.

Finally, the commercial availability of the chemical amygdalin from drug supply houses cannot provide a buttress for the district courts finding that laetrile was commercially marketed prior to October 9, 1962 (Pet. App. at pp. 29a-30a note 21). As Dr. Carl Leventhal made clear on the record in the rulemaking proceeding, the commercial availability of a chemical used for drug formulation purposes "does not establish protection under a grandfather clause for a finished dosage form of that chemical when it is labeled and offered for drug use." [82] Dr. Leventhal illustrates as follows:

> In this regard amygdalin is no different from any other chemicals and botanical substances from which newer preparations are derived. For instance, rauwolfia serpentian, a climbing shrub, contains in its root, reserpine, and has been used for centuries for medicinal purposes. However, when reserpine was extracted from rauwolfia reserpine, processed into a finished dosage form, and labeled for particular

[80] *See Id.*, Ad.R. 184, Ad.R 434, Ad.R. 201, and Ad.R. 431, (Affidavits of W. Sherwood Lawrence, M.D., Carl M. Leventhal, M.D., Robert S.K. Young, M.D., Bryant L. Jones).

[81] Durovic v. Richardson, 479 F.2d 247 (7th Cir. 1973), *cert. denied*, 414 U.S. 944.

[82] Ad.R. 434 at M 278.

> therapeutic uses, it was and is considered to be a new entity. The same is true of Laetrile or Vitamin B-17 for these drugs are different in not only their composition and dosage form, but bear labeling claims which were not associated with the ancient botanical sources.[83]

The ingredients used to manufacture the alleged cancer drug may have been available commercially but the commercially available substances were not sold as treatment for cancer.[84] It is the product produced from the various

[83] *Id.* at page M 278-79; see Ad.R. 416 at M 70-71.

[84] Ad.R. 434 at M 278-79; Ad.R. 416 at M 70-71.

The commercially available chemical compounds referred by Dr. Burk, the bitter almond listed on the "GRAS" list (Generally Regarded As Safe) of the FDA, is an oil used for flavoring and contains no amygdalin. It is not as suggested by Dr. Burk, laetrile Affidavit Exhibits I and J. Further, the oil of bitter almond compound referred to in the Merck Index is not the compound suggested for cancer treatment by Mr. Krebs. And the references to its use in Egypt or Russia for malignancies is pure and unsubstantiated hearsay. Ad.R. 434, Ad.R. 435. (Testimony of Richard H. Lange, M.D.) Indeed, the use in Russia was of a sweet almond mixture thought to be a narcotic. Ad.R. 434 at M 278. The claim made by the laetrile proponents in the FDA proceedings that the drug is grandfathered because it was contained in the Merck Index or used by the ancient Egyptians were in substantial part presented for court decision in Hanson v. United States, 417 F. Supp. 30, 36 (D. Minn. 1976). Unpersuaded, the court stated:

> The only evidence presented by the plaintiffs to try to establish that their tablets and vials of laetrile are exempt under the "grandfather" clause of § 321(p)(1) consists of the 1896 edition of Merck's Index and hearsay concerning the use of amygdalin during historical times dating back to the ancient Egyptians. This evidence is patently insufficient to demonstrate that the exemption applies. Merck's Index contains no information about the intended use of amygdalin, providing only certain facts as to its physical appearance, melting point, and source. The only reference to the conditions of its use is the phrase "Keep well stoppered." There is no indication therein that amygdalin in tablet form or in liquid form was in use for any purpose whatsoever; there is certainly no indication that amygdalin liquid was being injected intravenously into human beings or that amygdalin tablets were being ingested

available chemical compounds that is the allegedly cancer active agent to be evaluated, not the independent chemical ingredients.

4. Laetrile Is Not Entitled To A Grandfather Exemption Under The 1962 Drug Act Amendments Because The Drug Has Never Been Generally Recognized As Safe For The Treatment Of Cancer Either In Terms Of Toxicity Or Effectiveness

a. *The general recognition standard.* The elements required for general recognition of safety are correctly stated by the Commissioner in his decision at Pet. App. 155a:

> . . . for a drug to be generally recognized as safe it must have accumulated at least the amount of evidence and safety that would be required for the approval of a new drug application and that evidence must be generally available to the community of experts through publication in the scientific literature. In order for a new drug application for a drug to be approved, there must exist as to that drug "adequate tests by all methods reasonably applicable" that show the drug's safety (21 U.S.C. 355(d); cf. 21 CFR 314.111(a)(1))

The Commissioner's criteria tracks this Court's decision in the *Hynson* case. This Court in *Hynson* conceded that while Section 201(p) of the Act was both "quantitative and qualitative", on its face it failed to offer definitive guidance to the FDA with respect to its enforcement because a definition of what constitutes "general recognition" among experts was not to be found in the Act.

by human beings. In short, there has been no showing by the plaintiffs that laetrile tablets or liquid were "subject to" the Act prior to the enactment of § 321(p)(1), and no showing that "at such time its labeling contained the same representations concerning the conditions of its use."

Consequently, this Court looked to the overall statutory scheme of the Act and the overriding purpose of the 1962 Amendments and then articulated the standard to be applied, namely, that general recognition by experts presupposes an expert consensus founded upon substantial evidence as defined in Section 505(d) of the Act. 412 U.S. at 632. The elements of substantial evidence as set forth in that Section of the Act consists of adequate and well-controlled investigations, including clinical investigations by experts qualified by scientific training and experience to evaluate the drug involved, in this case for safety. The quality of these investigations should be such that the experts can conclude from them whether the drug will, in this case, be safe under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling. The scientific evaluation criteria articulated by this Court affords to the consumer the protections envisioned by then President Kennedy when he recommended the strengthening of the federal drug laws. "The physician and consumer should have the assurance, from an impartial scientific source, that any drug or therapeutic device on the market today is safe and effective for its use; that it has the strength and quality represented; and that the accompanying promotional material tells the full story—its bad effects as well as its good." (1962) U.S. Code Cong. & Admin. News, 4143-4144.[85]

[85] *See also* Pharmaceutical Manufacturers Ass'n v. Richardson, 318 F. Supp. 301, 307 (D. Del. 1970), in which the court cited witnesses before the hearings leading to the 1962 Drug Amendments corroborating President Kennedy's call for impartial judgments on drugs: "(A) collection of impressions will (not) furnish the truth . . . (T)his approach did not prevent doctors from having unbound faith in the curative powers of leeches for hundreds of years before scientific evaluation became the preferred means of judging efficacy of therapy . . . (The) magnitude of sales of a drug after vigorous promotion is no recommendation for its usefulness or efficacy . . ."

[Footnote continued on page 58]

The district court pays lip service to the general recognition criteria but its application of that criteria falls short. The district court relies not on the scientific consensus reflected in the record as a whole, from experts qualified by scientific credentials and recognition of their status by their peers, but rather on selective ancedotal experiences and submissions of laetrile proponents which are not supported by the objective scientific testing and respected publication criteria which are required by this

[85] [Continued]

See also, the opinion of Judge Smith in United States v. Articles of Food and Drug, 372 F. Supp. 915, 920-921 (N.D. Ga. 1974):

Quite properly, it is simply not enough to show that some people, even experts, have a belief in safety and effectiveness. *A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea. To remove the aberrations in uniformity which can result from a well-staged "swearing match," the law requires more.* Indeed, it has been heretofore held that the purpose of the normal inquiry is not to determine safety and effectiveness at all, but to ascertain the *drug's general reputation in the scientific community for such characteristics.* United States v. 41 Cases, More or Less, 420 F.2d 1126 (5th Cir. 1970); AMP, Inc. v. Gardner, 389 F.2d 825 (2nd Cir. 1968), cert. den., 393 U.S. 825, 89 S.Ct. 86, 21 L.Ed.2d 95 (1968). It is certain that a conflicting reputation is insufficient to establish general recognition. United States v. An Article of Drug—Furestrol Vaginal Suppositories, 294 F.Supp. 1307 (N.D. Ga. 1968), aff'd 415 F.2d 390 (5th Cir. 1969).

Therefore, what is required is more than belief, even by an expert; it is a general recognition based upon substantial scientific evidence as delineated in the regulatory guidelines. 21 CFR § 130.12. Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 93 St. Ct. 2469, 37 L.Ed.2d 207 (1973). There is no reason to differentiate the holding in *Hynson* between human drugs, and animal drugs. United States v. 14 Cases—Naremco Medimatic, 374 F.Supp. 922 (W.D. Mo., Number 2806, January 29, 1974). Public health considerations are similar. Further, logic would dictate no lesser standard after-the-fact than in securing an application. Indeed, the reasoning of the Supreme Court appears to be that "the reach of scientific inquiry" is the same whatever the forum. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645(b), 93 S.Ct. 2488, 37 L.Ed. 2d 235 (1973). [Emphasis added; footnote omitted.]

Court. In contrast, in arriving at his decision that there is no general recognition of the safety of laetrile, the Commissioner, as detailed below, scrutinized the record as a whole and evaluated the evidence quantitatively and qualitatively by application of the standards obtained in the statute as interpreted by this Court.

b. *The safety standard.* Where life-threatening illnesses such as cancers are involved, satisfaction of the safety standard of the grandfather clause must include a showing that the drug is both effective and non-toxic. The effectiveness requirement is discussed at pp. 15-18, *supra.* Briefly, at the hearings on the 1962 drug amendments, Secretary Ribicoff informed the Committee considering the bill that where progressive of life-threatening diseases such as cancer were involved, the administrative agency already required a showing of effectiveness as well as drug safety. The Senate report on the bill establishes that this administrative practice was expressly preserved vis a vis the new drug amendments: "The provisions of the bill are in no way intended to affect any existing authority . . . to consider and evaluate the effectiveness of a new drug in the context of passing upon its safety" (1962) U.S. Code Cong. & Admin. News at 2892. If effectiveness, as found by the district court as a matter of law (Pet. App. at page 28, note 18) could not be considered by the Commissioner in passing upon the "safety" of a drug intended for cancer, the Commissioner's pre-existing authority would certainly be "affected". His authority would be diminished. The language of the Committee interpreting the reach of the proposed legislation permits no such result.

Further, the requirement that drugs used in treatment of life-threatening diseases be effective in order to meet the "safety" standards of the 1962 grandfather exemption was squarely addressed in the *Durovic* decision. After recounting the administrative interpretation ac-

corded by the FDA to the safety requirement and after reviewing pertinent legislative history, the Court of Appeals in *Durovic* concluded:

> Bearing in mind the weight properly accorded to administrative construction, and Congressional awareness of the administrative view that the concept of safety in the law before the 1962 amendments included the concept of effectiveness for its indicated use where the drug is offered for use in the treatment of life-threatening disease, we think the definition of new drug before the amendments should be construed accordingly. It would follow that a drug offered for use in the treatment of cancer is now, and was before the amendments, a new drug unless it has achieved general recognition among the experts as safe and effective for such use.
>
> Under that analysis, the status of a drug offered for such use would be subjected to the same test before and after the amendments, and the grandfather clause would have no effect on it.[86]

The record in the rulemaking proceeding supports the Commissioner's decision that there exists an overwhelming consensus among qualified experts that laetrile was not generally recognized as safe in terms of effective for the treatment of cancer on October 9, 1962. Typical of the views of qualified experts toward laetrile is that of David T. Carr, M.D., a Professor of Medicine at the Mayo Medical School with wide experience in the cancer field. According to Dr. Carr:

> I am informed and understand that amygdalin is a cyanogenic glycoside. Cyanogenic glycosides are chemicals which contain in their molecular structure a sugar, a non-sugar, and the cyanide group, (—C ≡N). I know of no cyanogenic glycoside that is generally recognized as safe and effective for the prevention, treatment or cure of cancer, for the relief of pain associated with cancer, or for any medical purpose. The composition of the cyanogenic glycosides, in general, and of amygdalin, in particular, is such that I do not recognize them, and they are not generally recognized among experts qualified through scientific training and experience to evaluate drugs, as safe and effective for the treatment of cancer, for propylaxis against cancer, for relief of pain associated with cancer, or for any medical use. Neither amygdalin nor any other cyanogenic glycoside was generally recognized as safe for any such uses on October 19, 1962. None of these substances has ever been so recognized. The scientific literature contains no reports of adequate, well-controlled, scientific studies, or other evidence upon which such recognition may be predicated. I know of no recognized medical test in which use of amygdalin or any cyanogenic glycoside is recommended. I know of no medical school where use of these substances is taught. I know of no expert in cancer chemotherapy who is of the view that there is evidence these substances have any useful effect in treating cancer. I know of no report in the scientific literature describing an adequate, well-controlled study which demonstrates that amygdalin or any cyanogenic glycoside is safe and effective. Furthermore, I know of no cancer expert who would want a member of his family or himself to be treated with amygdalin if cancer should develop.[87]

[86] 479 F.2d at 250 (footnotes omitted).

[87] Ad.R. 176 at 4E, *see also* affidavits of: Robert C. Eyerly, M.D. (Ad.R. 167); George J. Hill, II, M.D. (Ad.R. 17); David T. Carr, M.D. (Ad.R. 176); John T.P. Cudmore, M.D. (Ad.R. 178); Bernard T. Korbitz, M.D. (Ad.R. 181); W. Sherwood Lawrence, M.D. (Ad.R. 183); Carl M. Leventhal, M.D. (Ad.R. 184); Daniel S. Martin, M.D. (Ad.R. 185); Joseph F. Ross, M.D. (AF-21 at 6-8); Philip S. Schein, M.D. (Ad.R. 191); Michael B. Shimkin, M.D. (Ad.R. 192); Jesse L. Steinfeld, M.D. (Ad.R. 194); C. Chester Stock, Ph.D. (Ad.R. 195); Alfred Suffer, M.D. (Ad.R. 266); Susan J. Mellette, M.D. (Ad.R. 420).

As noted above, it is considered particularly significant by the courts in determining the presence or absence of general recognition by experts as to safety whether adequate and well-controlled investigations of the drug have been accomplished and whether there is present a body of credible literature affirming safety.[88] The record in this case is devoid of evidence establishing that such investigations as toxicity/efficacy have been accomplished. To the contrary, the record abounds with sworn testimony by specialists well acquainted with the relevant literature and the state of expert opinion concerning cancer research, who declare without exception that no recognized expert in the field of cancer believes now or has ever believed that laetrile is safe or effective for the treatment of that disease. In the opinion of many experts, laetrile is highly toxic when taken orally.[89] Other experts note that there is a lack of evidence establishing that laetrile is non-toxic when taken parentally. According to the affidavit of Thomas H. Jukes, Ph.D.:

> Most items used as foods are not safe for injection, and amygdalin under the name, "laetrile", is frequently injected into cancer patients, apparently without immediate toxic effects. The toxic effects of injecting foreign substances may not show up for months or years. To be safe for injectable purposes, a compound must be shown by means of long-term toxicity tests not to produce pathological changes. No such data are available for amygdalin. (Ad.R. 416 at 1756.)

In this respect, it must be kept in mind that the grandfather exemption requires a positive showing that

[88] U.S. v. 1,048,000 Capsules More or Less, 347 F. Supp. 768, 771 (S.D. Tex. 1972).

[89] See e.g., Affidavits of Joseph F. Ross, M.D., Ad.R. 190, Chester Stock, Ph.D., Ad.R. 195, Donald C.S. Tan, M.D., Ad.R. 197, Exhibit 5. And see the chart on general recognition of safety at pp. 69-71, *infra*.

a drug had been generally recognized by qualified experts as non-toxic. There is no "presumption" of such general recognition; it is not neecessary to affirmatively demonstrate toxicity. Rather, the burden of proof remains on those who seek to invoke the grandfather exemption. Such an affirmative showing is absent from this record. Additionally, where there has been little testing of a drug or where there is a dearth of medical literature on the question of its toxicity, the drug cannot possibly meet the grandfather requirements of general recognition among qualified experts. *United States* v. *41 Cases, More or Less*, 420 F.2d 1126 (5th Cir. 1970). See discussion at pp. 56-59, *supra*.

Finally, a recent Massachusetts court order in a case involving a minor treated with laetrile and a coroner's report of a laetrile patient death attributed to acute cyanide poisoning both support the emerging profile of laetrile as a toxic and dangerous substance.

In the case involving the child [90] Judge Guy Volterra by Interlocutory Order of January 22, 1979, after finding that the child's parents were giving him laetrile which "is dangerous to health", directed the parents to submit the minor to urine thiocynate and serum thiocynate tests to monitor whether the child is at risk of chronic cyanide poisoning.[91] After receiving the report of the physician, by order of January 31, 1979, Judge Volterra found that the child indeed was suffering from chronic cyanide poisoning stemming from laetrile therapy: "The Court has accepted into evidence today a new laboratory test which indicates a level of free cyanide in the child's blood at twice the normal level." [92]

[90] Custody of a Minor, Superior Court Civil Docket No. 78-6815, Commonwealth of Mass., Plymouth Division, The Courts orders of January 22, 1979 and January 31, 1979 are appended hereto as Appendix C.

[91] *Id.*

[92] *Id.*

The Coroner of Alameda County, California, in a report attached as Appendix B, determined that a female cancer patient who was receiving laetrile treatment died of cyanide intoxication. The cyanide levels in her blood were 3/8 mcg/ml. The deceased's laetrile treatment commenced in March of 1978 with a dosage of 9 grms every day for 30 days, then reduced to 3 grms thrice weekly, later reduced to twice weekly and she was on the last course of treatment (once a week injections) when she died. If the deceased was unable to come in for injections, her instructions were to take 1000 mgm tablet of laetrile.

As graphically demonstrated on Tables A and B which follow, laetrile has not satisfied the general recognition criteria for safety either in terms of toxicity or effectiveness, neither has it shown consistency in formulation, purity, mechanism of action, labeling, claims, dosages, or method of administration, all of which are required to gain a grandfather exception. The record supports the Commissioner's denial of such an exception and the error of the district court in granting an exemption.

REQUIREMENTS FOR THE 1962 GRANDFATHER CLAUSE

Dates	Mechanism (Rationale) of Drug Action	Label/Pamphlet claims for Laetrile	Formulation	Method of preparation (Reconstitution)	Dosage	Route (Method of) Administration	Use As An Investigational Drug/Not Commercially M'kted	Laetrile Label & Pamphlets—Representation Safety/toxicit
1920's			apricot extract containing "emulsin", "amygdalese", "prunase", "Pectinase" (1)			IV-single injection process (8)		
1926			apricot extract called "sarcarcinase" which was amygdalin + 1 glucosidase (2) "sarcarcinase" is less than 5% amygdalin (3)					
1929			apricot extract rich in glucosidose & amygdalin (4)					toxic-IV (5)
1932					50mg (6)			
1936			amygdalin purity is 66% (7)					
1952			amygdalin minus emulsin (11)	isotonic solution (28)	50mg every 3-5 days (16) 20mg (17)	IV of cyanogenetic glucoside ff. in 5 minutes by IV of the enzyme Beta-glucosidase (9) IM injection ff. in ½hr. by IM injection of beta-glucosidase (10)	investigational use (12) Krebs foundation set up in 1963 "to foster the investigation of Laetrile." (13) Laetrile first tried in humans in June of 1952 (14)	not for oral administration (15)
1953					100-250mg every 3 days (18)			
1954		pallative agent not for oral administration (19)				IM injection or near but not into lesion (24)		extremely toxic orally (20)
1955			prunasin biosynthesized (21) amygdalin lyophilized (22)			IV injection of Laetrile ff. by Beta-glucosidase (23) IM injection (23) tamponade (23) Iontophoresis (23)		
1952-1955			prunasin—amygdalin with one molecule of glucose instead of two (25)					
1958			1-mandelo nitrile-beta-glucuronic acid (26)		2mg per lb. of body weight daily or every other day (27)			
1959		reduces size of malignant tumor (71)			2,000mg (71)			
1960			amygdalin purity is 99.8% (35)					
1961								
1962	Beardian thesis (29) Krebs cyanide theory (72)	pallative agent not for oral administration (30) not to be employed to the exclusion of other cancer treatment modalities (31) applicable to carcinomas, sarcomas, hodgkins disease (32) not recommended for the leukemias (32)	N,N diisopropylammonium iodide and saccharides in addition to amygdalin (33) Of 4 identically labeled-laetrile samples, 2 contained iodine as an additive and 2 did not (34)	isotonic solution (36)	1000mg (28) 1-2 grams every day (37) 3,000-5,000mg. (38) 10-20mgs. of the glucoside amygdalin for every lb. of patient's weight, daily (39)	IV or IM injection (40)	All amygdalin compounds used from 1926-1962 were shipped for "investigational use only" (41)	not to be taken orally, it is extremely toxic by that route of administration (42) "Laetrile is relatively non-toxic when administered parenterally." "Orally it is extremely toxic due to the release of hydrogen cyanide on contact with the hydrochloric of the gastric juices." (43)
1963								
1965	Cancer is a deficiency disease and laetrile is a vitamin for that deficiency (45)	kills the cancer cell (47) Avoid other cancer therapies; only take Laetrile (48)	preparation only concontained amygdalin (49) preparation contained 87-98% amygdalin with varying amounts of sucrose, phenol and diisopropyl ammonium iodide (50) US/Canada product labels same: A-B-Cyanogenetic glucoside; US contained 87 + 2% amygdalin; Cnda -98 + 2% amygdalin; US also contained phenol, iodide, sucros; the different formulation reflected in "marked biochemical difference" in testing. (51)	water (52)	10-15 mgs per. lb. patient weight (53) 20mgs. per lb. body weight (53)	oral (44) Interarterial enemas oral (54)		Krebs Laboratories offers oral Laetrile and states that it is non-toxic (45)
1969	Passwater's cellular oxidation and fermentation process (72)		amygdalin contained not less than 96% of C20H2NO (55) Amygdalin MF (56)		size/frequency of dosage has not been precisely determined (57) 3-6grms/70kg every 24 hrs (57)		"amygdalin is still an investigational drug" (58)	
1970					3-6grms/day (59)	IV injection not orally (60)	investigational drug (61)	
1971					800mg./day (62)	oral capsules (63)		Laetrile capsules: oral use-non toxic cyanide glucoside (64)
1976			Unreliability of formulation (65)					
1977	Brehhman & Dardymor's adaptogenic glycosides stimulating the production of immune bodies (72)	prevent, control cancer, pain relief, appetite increase, weight gain, feeling of well being (66) a Laetrile is not a cancer cure, it may effect control (66) b	formula variability of 14 to 87% amygdalin in injection solutions formula variability of 42-450 mg. amygdalin per 500 mg. tablet in oral medication (67) a		6-9 grams/day (67) b 17000milligrams (68)	IV injection supplemented lets (69) by oral tab-		
1978			Laetrile chemical formula: C14H15NO7 (73) Amygdalin chemical formula: C20H27N11 (73)		9 grams (day) reduced to 3 grams (twice weekly) reduced to 2 grams (biweekly or 1000mgm orally (70)	IV oral (70)		

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REFERENCES FOR TABLE A

(1) Ad. R. 260 at p. 1-2
(2) Ad. R. 167 Attch. 13
(3) Ad. R. TS26
(4) Ad. R. 183 Attch. 7 at p. 23
(5) Ibid.
(6) Ad. Tr. 238
(7) Ad. R. 183 Attch. 13¶ Ad. R. 184 at p. 9 and Exh. 6
(8) Ad. R. 184 Exh. 6 at p. 2
(9) Ad. R. 183 Attch. 7 at p. 24
(10) Ad. R. 388 Exh. Nos. 2, 4
(11) Ad. R. 183 Attch. 7 at pp. 23-26
(12) Ad. R. 388 Exh. 2
(13) Ad. R. 184 Exh. 5 at p. 3.
(14) Ad. R. 184 at p. 9 & Exh. 5
(15) Ad. R. 184 Exh. 5 at p. 3.
(16) Ad. R. 167 Exh. 2
(17) Ad. R. 183 Attch. 6
(18) Ad. R. 388 Exh. Nos. 3, 4
(19) Ad. R. 388 Exh. 4
(20) Ad. R. 388 Exh. Nos. 4, 5
(21) Ad. R. 183 Attch. 7 at p. 26
(22) Ad. R. 183 Attch. 13
(23) Ad. R. 183 Attch. 7 at pp. 26-31; Ad. R. 184 at p. 9
(24) Ad. R. 388 Exh. 4 at pp. 6-7
(25) Ad. R. 183 Attch. 7 at p. 26
(26) Ad. R. 183 Attch. 7
(27) Ad. R. 167 Exh. 2
(28) Ad. R. 183 Attch. Nos. 6 & 16 at p. 22
(29) Ad. R. 201 at H234; Dorr, Paximos "The Current Status of Laetrile" 89 Annals Of Internal Medicine 390-391 (1978)
(30) Ad. R. 201 at H.232 & Attch. 1
(31) Ad. R. 201 at H.232
(32) Ad. R. 201 Attch 1
(33) Ad. R. 201 at H.232; Ad. R. 183 Attch. Nos. 17, 16 at p. 21.
(34) Ad. R. 183 Attch. 16 at pp. 27-28
(35) Ad. R. 183 Attch. 13; Ad. R. 184 at p. 9 and Exh. 6
(36) Ad. R. 201 at H.232
(37) Ad. R. 201 Exh. B at 104
(38) Ad. R. 167 Exh. 2
(39) Ad. R. 183 at p. 4 & Attch 8 at p. 3.
(40) Ad. R. 201 at H.233
(41) Ad. R. 167 Attch. 3
(42) Ad. R. 183 at p. 16
(43) Morrone, John A., M.D., "Chemotherapy Of Inoperable Cancer; A Preliminary report of 10 Cases Treated With Laetrile, 20 Journal of Experimental Medical Surgery 299-308 (1962)
(44) Ad. R. 183 Attch. 4C
(45) Ad. R. 183 Attch. 4C
(46) Ad. R. 201 at H.234; Annals supra note 29 at p. 391
(47) Ad. R. 201 at H.232 and Exhb. C
(48) Ad. R. 201 at H.233
(49) Ad. R. 201 at H.232
(50) Annals, supra note 29 at p. 389-390
(51) Ad. R. CO251 Attch. 14 "Supplementary Report by the Cancer Advisory Council on the treatment of cancer with Beta-cyanogenetic Glucosides" Part III, Study of Its Physiochemical and Biochemical Properties, Table 1 at 22 and at pp. 19-26. See also 92 Canadian Med. Assoc. Journal 1057-1061 (May 16, 1965)
(52) Ad. R. 201 at H.232 and Exh. C
(53) Ad. R. 201 Exh. C
(54) Ad. R. 201 at H.233 and Exh. C
(55) Ad. R. 216 at 375

(56) Ad. R. 174, Attch. 9
(57) Ad. R. 216 at 384; Ct. R. 1416 at 384
(58) Ad. R. 384 at 374
(59) Ad. R. 183 Attch. 10
(60) Ibid.
(61) Ad. R. 184; Ad. R. 301; Ad. R. 431
(62) Ad. R. 183 Attch. 9
(63) Ibid.
(64) Ibid.
(65) New England Journal of Medicine issue of November 25, 1966 at p. 1264, comment by physicians at United States Center for Disease Control
(66-a) Kennedy Subcommittee Laetrile Hearings, July of 1977 at pp. 246-247, 271-272 (J.A. Richardson, M.D.); pp. 295-297 (Robert. Bradford, Committee Free Choice Cancer Therapy)
(66-b) Bradford, supra, Laetrile Hearings, at p. 295
(67-a) Annals, supra note 29
(67-b) Annals, supra note 29 at 395
(68) Ad. Tr. 238
(69) Annals, supra note 29 at 395
(70) Coroners Report, Appendix B hereto.
(71) Ct. R. 1416, McNaughton Foundation Drug Brochure at 387
(72) Ct. R. 1507, booklet "Amygdalin (Laetrile) Therapy" Bruce W. Halstead M.D. at pp. 25-29
(73) Id. at pp. 4-5.

TABLE B:

GRANDFATHER RIGHTS: LACK OF GENERAL RECOGNITION OF SAFETY/EFFICACY

Safety/Efficacy *

Arthur I. Holleb, M.D., Sen. V.P. for Med. Affairs, ACS (Pet. App. 127a-128a)
R. Lee Clark, M.D., Pres. ACS (Pet. App. 128a-129a)
Frederick N. Silverman, M.D., Chmn. Comm. Neoplastic Diseases Am. Academy of Pediatrics (Pet. App. 129a)

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* The qualify for an exemption from new drug status, Laetrile on October 9, 1962 would have to have been generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use under the conditions prescribed, recommended or suggested in the labeling thereof. For a drug to be recognized as safe, it must have accumulated evidence of safety through adequate tests and that evidence must be generally available to qualified experts through publication in the scientific literature (Pet. App. 155a). Bearings upon safety criteria is whether there is general recognition of Laetrile's use, formulation, conditions or use (Pet. App. 201a-204a). Further, as discussed at pp. 14-18 supra, safety in terms of life-threatening illness is by court and administrative construction prior to 1962 held to include effectiveness. This table scrutinizes general recognition of safety both as to the record on "effectiveness" as well as "toxicity". Finally, it should be noted (Pet. App. 114a) that this general recognition standard applies to adequate and well-controlled clinical (human) trials, not animal tests. However, the effects noted in animal tests reinforce the experts view on the toxicity of Laetrile. See e.g., Dorr, Paximos "The Current Status of Laetrile" 89 Annals of Internal Medicine 393-394 (1978), Lewis "Laetrile" 127 Western Journal of Medicine 55 (1977), Fenselau et al "Cancer Causing in Animals: Mandelonitrile B-Glucuronide: Synthesis and Characterization, 198 Science 625 (1977).

William R. Barclay, M.D., American Medical Ass'n (Pet. App. 129a-131a)
W. Sherwood Lawrence, M.D., St. of Calif. Cancer Adv. Cncil (Pet. App. 131a)
Jonathan Rhoads, M.D., Chm. Presidents Nat'l Cancer Adv. Bd. (Pet. App. 131-132a)
Jesse Steinfeld, M.D., Dean, Sch. Med., Med. College of Va. (Pet. App. 132-133a)
Richard H. Lange, M.D., Chief, Nuclear Med., Ellis Hosp. (Pet. App. 133a-134a)
M. Shimkin, M.D., Prof. Sch. Med., U. of Calif., San Diego (Pet. App. 134a)
B. Korbitz, M.D., Chief, Chemotherapy Sec., Neb. Med. Hosp. (Pet. App. 134a-135a)
Susan Mellette, M.D., Assoc. Prof. Med., Oncology, Med. Coll. of Va. (Pet. App. 135a-136a)
D. Martin, M.D. (Pet. App. 136a-137a)
J. Wallace, Jr., M.D., Dir. Cancer Control & Rehab., Roswell Park (Pet. App. 137a)
J. T. P. Cudmore, M.D. (Pet. App. 137a-138a)
Sidney Weinhouse, Prof. Biochem., Temple (Pet. App. 138a-139a)
B. L. Jones, M.D., Med. Dir. U.S. Public Health Serv. (Pet. App. 139a-140a)
G. J. Hill, II, M.D., Prof. Marshall Univ. (Pet. App. 140a-142a)
V. DeVita, Jr., M.D., Director, Division of Cancer Treat., NCI (Pet. App. 142a-143a)
R. L. Mecklenburg, M.D., Dir., Nuclear Med., Wilmington Med. Ctr. (Pet. App. 143a)
R. C. Eyerly, M.D., Geisinger Clinic (Pet. App. 143a-144a)
See also Pet. App. 145a-149a, 209a-211a.

Safety/Toxicity

See Generally Pet. App. 154a-162a, 201a-206a
W. Sherwood Lawrence, M.D., State of Calif. Cancer Adv. Council (Pet. App. 156a-158a)
R. S. K. Young, M.D., Ph.D. (Pet. App. 158a-160a)
Carl M. Leventhal, M.D. (Pet. App. 160a)
J. F. Ross, M.D. (Pet. App. 162a)

Ingestion of apricot pits

Laetrile, Apricot Pits, and Cyanide Poisoning, New England Journal of Medicine 1264 (Nov. 25, 1976)
Cyanide Poisoning From Ingestion of Apricot Kernels—California Morbidity & Mortality, Center for Disease Control, HEW Doc. of 12/19/75
Annals of Internal Medicine, see note below at 391.

Laetrile: oral medication

Annals of Internal Med., see note below at p. 391.
Smith et al "Laetrile Toxicity: A Report of Two Patients" 72 Cancer Treatment 169 (1978) (Case 2, toxicity symptoms resolved within 48 hours of discontinuing Laetrile).
D. Maxwell, M.D., "Increased Cyanide Values In A Laetrile User" 119 CMA Journal 18 (July 8, 1978) (normal cyanide values 0.01-0.02 mg/dL; Laetrile patient experiencing toxicity levels 0.6 mg/dL; Patients who have died have cyanide levels of 0.26 to 3/1 mg/dL).
Alameda County Coroner's Report, Appendix B hereto. Patient taking oral laetrile medication (1000 mgm tablets) died of cyanide intoxication with a blood level of 3.8 mcg/ml.

Laetrile by injection

Annals of Internal Medicine, see note below at p. 391.
Smith "Laetrile Toxicity" supra, Case 1.

III. THE USE OF LAETRILE IN CONNECTION WITH ONE'S PERSONAL HEALTH CARE IS NOT PROTECTED BY THE CONSTITUTION

A. Overview

The district court in its decision found a general right to use laetrile: "By denying the right to use a nontoxic substance in connection with one's own personal healthcare, FDA has offended the constitutional right of privacy" (Pet. App. 14a).[93] In doing so, the district court adopted the position of the laetrile proponents below that the premarketing requirements of the Act violate the cancer patient's right to privacy by inhibiting access to drugs which have not been proven safe and effective. This contention [ratified by the district court, and scrutinized here as an alternative avenue of affirmance or, as the Society submits, rejection of the court of appeals decision] raises the issue of whether the amorphous right of privacy encompasses the right to choose unsafe and ineffective drugs.

Traditionally, regulating health has been viewed as a valid and important exercise of the police power.[94] As such, health regulations have been upheld upon a demonstration of a rational or reasonable relationship between the statute and the purpose of the legislation.[95] However, should this Court decide that a patient has a fundamental

[93] The error of the district court in assuming that laetrile is non-toxic is discussed *supra* at pp. 59-71. The effects of permitting access to laetrile to the terminally ill on the public health and welfare are treated *supra* at pp. 23-33.

[94] "It is elemental that a State has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone therein. It is a vital part of the State's police power." Barsky v. Board of Regents of New York, 347 U.S. 442 (1963).

[95] *See* Goldblatt v. Town of Hempstead, 369 U.S. 590, 594 (1962); Williamson v. Lee Optical Co., 348 U.S. 483 (1955).

right to take a drug which has not met the safety and efficacy requirements of the Act, and thereby evoke strict judicial scrutiny, the government must justify its intrusion upon the patient's choice by demonstrating a compelling interest in the pre-marketing standard.[96] The American Cancer Society maintains that the safety and efficacy requirements should be judged under the rationale basis standard.[97] However, should this Court elect to expand "right of privacy" to include access to drugs which have not met the FDA premarketing requirements, the national interest in assuring the safety and effectiveness of a drug before it reaches the consumer and the causal nexus between the premarketing standards and the purpose of the legislation indicate that the compelling state interest standard has been met.

B. There Is No Absolute Right To Do With One's Body As One Chooses

As this Court noted in *Paris Adult Theatre I.* v. *Slayton*:

> The State statute books are replete with constitutionally unchallenged laws against prostitution, suicide, voluntary self-mutilation, brutalizing "bare fist" prize fights and duels, although these crimes may only directly involve "consenting adults". Statutes making bigamy a crime surely cut into an individual's freedom to associate but few today seriously claim that such statutes violate the First Amendment or any other constitutional provision.[98]

[96] Kramer v. Union Free School District, 395 U.S. 621, 627 (1969), Shapiro v. Thompson, 394 U.S. 618, 634 (1969).

[97] This Court applied this standard when considering the constitutional implications of a state physician/patient identification procedure with the prescription of Schedule II drugs. Whalen v. Roe, 429 U.S. 589 (1977). The rational basis test was also applied when the Court considered the validity of a state statute outlawing a particular abortion procedure. Planned Parenthood v. Danforth, 428 U.S. 52 (1976).

[98] 413 U.S. 46, 68 (1973).

This Court has upheld compulsory military service,[99] compulsory vaccinations,[100] and compulsory sterilization.[101] Blood transfusions have been authorized despite the patient's unwillingness to consent.[102] Courts have universally rejected the argument that there is a constitutional right to use marijuana in the privacy of one's own home.[103] In an analogous area, this Court has summarily affirmed a decision rejecting claims that state legislation requiring motorcyclists to wear protective helmets violated the right to privacy.[104]

These cases have rejected the argument that governmental imposition of self-protective regulations is an unconstitutional invasion of a person's autonomy and right to be let alone. They collectively indicate that the government has a supportable interest in limiting personal choice to protect an individual against the possibility of self-harm. In the case of drugs, such as Laetrile, where it is substantially more difficult for the individual to make an informed and rational judgment, this governmental interest would appear to be even stronger.

C. Cases Cited By The District Court Do Not Adequately Support Its Conclusion That There Is A Constitutional Right To Use Laetrile

In concluding that there is a constitutional right to use drugs which have not met the FDA premarketing

[99] Selective Service Law Cases, 245 U.S. 366 (1918).

[100] Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[101] Buck v. Bell, 274 U.S. 200 (1927).

[102] *See e.g.*, Application of the President and Directors of Georgetown College, Inc., 331 F.2d 1000 (D.C. Cir. 1964).

[103] See U.S. v. Drotar, 416 F.2d 914 (5th Cir. 1969).

[104] Simon v. Sargant, 409 U.S. 1020, summarily affirming 346 F.2d 277 (D. Mass. 1972) (three judge court). See Note "Motorcycle Helmets and the Constitutionality of Self-Protective Legislation", 30 Ohio State Law Journal 359 (1969).

requirements[105] the district court relied primarily[105a] upon Justice Douglas' reference to "the freedom to care for one's health and person" in his concurring opinion in *Roe* v. *Wade*[106] and *Doe* v. *Bolton*.[107] In an apparent attempt to shape the penumbra concept he first articulated in *Griswold* v. *Connecticut*,[108] Justice Douglas indicated

[105] The district court found a constitutional right to use a non-toxic substance in connection with one's personal health-care (Pet. App. 41a). The assumption that Laetrile is non-toxic has been substantially refused above, however, for the purposes of this discussion, we will assume non-toxicity.

[105a] The district court also suggested that the opportunity to take Laetrile comes within the right "to be let alone", first articulated by Justice Brandeis in his dissenting opinion in Olmstead v. United States, 277 U.S. 438, 478 (1928). This suggestion overlooks the context of which Justice Brandeis initially conceived that right. In his famous dissent Justice Brandeis contended that the makers of our Constitution:

> Sought to protect Americans in their beliefs, in their thoughts, their emotions, and their sensations. They confer, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. To protect that right every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment. And the use, as evidence in a criminal proceeding of facts ascertained by such intrusion must be deemed a violation of the Fifth.

The right to be let alone is then the right of an individual to be protected from governmental surveillance, intrusion and/or disclosure of private affairs. Read in context, the "right to be let alone" has entirely different constitutional underpinnings than those at issue with the drug Laetrile. Regulation of health and health care, unlike government surveillance, intrusion or disclosure of personal matters which are specifically prohibited by the Fourth and Fifth Amendments, is not only an area in which governmental action has traditionally been accepted, it is also an area in which government action is expected.

[106] Roe v. Wade, 410 U.S. 113 (1973).

[107] Doe v. Bolton, 410 U.S. 179 (1973).

[108] 381 U.S. 479 (1965).

his belief that the concept of liberty includes the following rights:

> (1) Control over the developement and expression of one's intellect, interests, tastes and personality; (2) freedom of choice in the basic decisions of one's life respecting marriage, divorce, procreation, contraception and the education and upbringing of children; and (3) freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll or lope.[109]

After asserting that this third group of rights are fundamental and subject to regulation only upon a showing of compelling state interest, Justice Douglas does not cite cases to the effect that freedom to care for one's health is among the fundamental rights subject to strict scrutiny under the Constitution. The discussion following the third group of rights concerns only freedom from bodily restraints, freedom of movement, and protection pursuant to the Fourth Amendment from governmental intrusion. The concept of health care is not delineated or defined by Justice Douglas. Further, Justice Douglas was not joined in his concurring opinion.

Significantly, later opinions of this Court in discussing the concept of liberty in the context of personal privacy have not subscribed in full to Justice Douglas' laundry list of fundamental rights.[110] In fact, only the task of protecting the familiar freedoms, which Justice Douglas recognized in his second group of freedoms, has required this Court to resort to the privacy rationale of *Roe*, *supra*. Specifically, Justice Rhenquist writing for the majority in *Paul* v. *Davis* characterized the activities the *Roe* Court found within the guarantee of personal privacy as dealing with "matters relating to marriage, procrea-

[109] 410 U.S. at 211-213.

[110] Paul v. Davis, 424 U.S. 693, 713 (1976).

tion, contraception, family relationships and child rearing and education. In these areas it has been held that there are limitations on the state's power to substantively regulate conduct." [111] Clearly, the right of privacy found in familial or social relationships differs markedly from the right that is involved when the individual desires to take a drug which may be toxic and whose efficacy has not been proved in a series of objective scientific tests.[112]

Furthermore, as observed by at least four commentators, recent Court decisions demonstrate a tendency to regard the right of privacy not as a penumbral product, but rather a right attendant upon the more explicit provisions of the Bill of Rights or as a right emanating from the due process clause of the Fourteenth Amendment.[113]

D. Decision To Undergo Treatment Versus The Right Of Choice Among Medical Alternatives

Illustrative of the principle that choice among medical alternatives is not at this time a decision within the zone of constitutionally protected privacy is this Court's holding in *Planned Parenthood* v. *Danforth*.[114] There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis.[115] However, the Court did not hold that the prohibition violated any right to privacy. It did not hold that, because the right of privacy encompasses a woman's decision to have an

[111] *Id.*

[112] See *supra* at pp. 56-59.

[113] Levy, Martin R. and Hectus, C. Thomas, "Privacy Revisited: The Downfall of Griswold", 12 University of Richmond Law Review 627 (1978); Hayman, Phillip B. and Barzelay, Douglas E. "The Forest and the Trees: Roe v. Wade and Its Critics", 53 Boston University Law Review 765 (1973).

[114] 428 U.S. 52 (1976).

[115] *Id.* at 79.

abortion, the state may not prohibit a particular abortion procedure. Rather, citing *Roe, supra*, the Court stated the issue before it as follows: "(W)hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health' ".[116]

The Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to the protection of maternal health. Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, the Court did not refer to any constitutional considerations of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by the Court solely on the basis of the medical evidence of its safety and effectiveness.[117]

Planned Parenthood thus stands for the proposition that although a decision of whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter to which privacy status does not attach and which may be regulated by government, provided a rationale basis for such regulation exists.[118]

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[116] *Id.* at 76.

[117] The voluminous record evidence discussed in Argument II, supra, on the safety and effectiveness of laetrile vis a vis the patient with life-threatening or terminal illness makes it clear that there is a reasonable relationship between the premarketing provisions of the Act and the public health and welfare.

[118] Similarly, in Eisenstadt v. Baird, 405 U.S. 438 (1972), where the Court held that unmarried individuals have a privacy right to purchase and to use contraceptives, the Court noted that the contraceptives themselves, if they are new drugs within the meaning of the Act would be subject to the premarket approval under Section 505, 21 U.S.C. § 355. Id. at 452. *See also* Whalen v. Rose, 429 U.S. 598 (1977).

In the instant case, the analogue of the right to decide whether to have an abortion is the right to decide whether to receive or forego cancer treatment. But although the decision whether to receive treatment may be constitutionally protected, the choice among treatment alternatives is not within the scope of the constitutional right to privacy. The issue is rather, whether "the regulation reasonably relates to the preservation and protection of maternal health." [119] Its analogue is whether the premarketing provisions of the Act reasonably relate to the preservation and protection of the health of the cancer patient.

E. The Governmental Interest In Protecting Individual Health And Public Health Provides Compelling Justification For The Application Of Pre-Marketing Requirements To Laetrile

Even where the Court has accorded "fundamental" constitutional protection to areas of private decision-making, it has recognized that those rights are not absolute; they may be limited by regulation serving compelling public purposes.[120]

1. *Protection Of Public Health*

Protection of public health has always been accorded special recognition by the courts as providing compelling justification for state regulation. The Court itself has recognized that where public health and safety are at stake, even fundamental rights may be regulated and restricted under the states police power.[121]

While finding that the right of privacy is "broad enough to encompass a woman's decision whether or not to termi-

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[119] Roe v. Wade, 410 U.S. at 163.

[120] *See* nn.94-97, *supra*.

[121] Roe v. Wade, 410 U.S. at 153-154, 162-163.

nate her pregnancy",[122] the Court in *Roe* maintained that at some point in the pregnancy the state's important interests in safeguarding health, in maintaining medical standards, and in protecting potential life become sufficiently compelling to sustain regulation of the factors that govern the abortion decision.[123] With respect to the health of the mother, the Court concluded that the "compelling" point is at approximately the end of the first *trimester*.[124] This conclusion was based on the medical fact that the risk of a woman's death in first *trimester* abortions appears to be at least as low as that in normal child birth,[125] while the increase in the hazards to abortion procedure in the second trimester justified imposition of state regulations. With respect to the state's interest in potential life, the compelling point was found to be at viability—which occurs approximately at the end of the second trimester. At this point the Court indicated that the state could even prohibit abortion except where necessary for the preservation of maternal life or health.[126]

These aspects of the holding in *Roe* are significant in light of the constitutional issue raised, for they reflect this Court's recognition of the government's compelling interest in protecting individual health, and in protecting the public health generally where individual conduct may adversely affect the well-being of others.[127] The authority

[122] *Id.* at 153.

[123] *Id.* at 154.

[124] *Id.* at 163.

[125] *Id.*

[126] *Id.* at 164-165.

[127] Even John Stuart Mill recognized that state regulation in the area of public health did not impermissibly infringe upon the choice of the individual. He contended that where, "there is a definite damage, or a definite risk of damage, either to an individual or to the public, the case is taken out of the province of liberty and placed in that of morality or law." J.S. Mill, On Liberty 100 (Liberty Arts Press 1956).

to protect individual health, and the public health generally, may be exercised to overrule the woman's personal decision to undergo a particular medical or surgical procedure during the second and third trimesters of pregnancy even when she is fully aware of the risks of the procedure, and is willing to take those risks.[128] An individual's decision to use Laetrile can stand on no higher constitutional level than the decision of a woman to have an abortion in the later stages of pregnancy.

The FDA seeks to prevent the use of Laetrile because its proponents have failed to meet the premarketing standards for drug approval which Congress established in Section 505 of the Act. The effectiveness standard, in particular, is designed to protect the public health by ferreting out "those drugs for which there is no affirmative, reliable evidence of effectiveness.[129] Laetrile falls within that class and its prohibition serves compelling public health purposes.

In the case of cancer, it has been established on the record that a significant number of patients can be cured or have their lives extended by the use of legitimate therapy, especially when treatment is begun as soon as possible after diagnosis. Ad. R. 173, 42 Fed. Reg. at 39798.[130] The availability of Laetrile serves to encourage delay among certain cancer patients in seeking effective therapy. 42 Fed. Reg. at 39799. Moreover, even among patients who begin treatment of their cancers with effective therapy, the readily acknowledged side effects of that therapy may cause them to cease to use such methods at a time when their application still may be successful, and turn instead to Laetrile—"the painless cure". 42 Fed. Reg. at 39799 and 39797. Because legitimate therapy

[128] 410 U.S. at 162-165.

[129] Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 616 (1973).

[130] *See* also statistics cited *supra* at notes 10, 30.

may be stopped, delayed or avoided, many cancer patients will die needlessly or prematurely; this fact alone provides compelling justification for prohibiting interstate transportation and sale of drugs such as Laetrile absent compliance with the premarketing standards.

F. Consent To Treatment With An Unapproved Drug Does Not Override The Government's Interest In The Pre-Marketing Requirements Of The Act

This Court has indicated that a patient's desire for and consent to a particular medical treatment would not be sufficient to override a statutory prohibition of the procedure where that prohibition reasonably relates to the preservation and protection of health.[131] Even where fundamental rights are at stake, this Court has held that compelling governmental interests will prevail over the interests of a consenting adult.[132] Together, the Court's rulings in *Planned Parenthood* and *Roe* indicate that the consent of a patient to treatment with Laetrile will not override the government's interest in the safety and efficacy provisions of the Act.

Further, measured against this record, the exercise of informed consent to take laetrile does not appear possible. Consent can only reach as far as the information it is based upon. For example, the federal regulations relating to informed consent[133] require that a patient be made aware of the benefits of a drug or its discomforts or risks. The district court's consent form does not provide for this information.[134] Further, this record, discussed *supra*, establishes not only that Laetrile is not generally recognized as safe or effective for any purpose, it also demonstrates that the lack of knowledge about

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[131] See cases nn.97, 106, *supra*.

[132] *Id.*

[133] 45 Code of Federal Regulations 46.103.

[134] Ct.R. 409-414, 423-480, 1505 and attachments.

specific toxicity effects by oral and injection administration makes it impossible to put together a valid consent form for its administration.

CONCLUSION

Statutes should be given their fair meaning in accord with the evident intent of Congress. *See e.g., United States* v. *Sullivan*, 332 U.S. 698 (1948) and *United States* v. *Raynor*, 302 U.S. 540 (1938). The court of appeals by writing the terminally ill out of the statute and the district court by its clearly erroneous application of the grandfather exemption and its perversion of the concept of right to privacy protections have construed the federal drug laws and the Constitution in a way that conflicts with the plain meaning, statutory intent and Court interpretation. The course of action advocated by these courts erodes the protections provided by the federal drug laws and poses a significant threat, particularly to those whose illness is life-threatening instead of terminal. For these reasons, the Government's petition to this Court should be granted; the decisions below should be reversed; the decision of the Commissioner should be found to be supported and the courts below directed to adopt that decision as properly declaring the status of the drug Laetrile.

Respectfully submitted,

GRACE POWERS MONACO
FAIRMAN, FRISK & MONACO
2600 Virginia Avenue, N.W.
Suite 301B
Washington, D.C. 20037

Attorney for the American
Cancer Society, Inc.

March 8, 1979

Appendices

STATUTORY APPENDIX

FOOD, DRUG AND COSMETIC ACT

Section 201(p), 21 U.S.C. § 321(p), provides in part:

> The term "new drug" means—(1) Any drug * * * the composition of which is such that such drugs is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.
>
> * * *

Section , 21 U.S.C. § 331(d) provides:

> (d) the introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

Section 505, 21 U.S.C. § 355, provides as follows:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.
>
> (b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which

have been made to show whether or not such drug is safe for use and whether such drug is effective in use * * *

* * * *

(d) If the Secretary finds * * *, that (1) the investigations, * * * required to be submitted to the Secretary * * *, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests * * * do not show that such drug is safe for use under such conditions; * * * (4) * * * he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) * * * there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based upon a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application * * *.

As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing.

Section 107(c)(4) of Public Law 87-781, 76 Stat. 798 ("1962 grandfather clause") provides:

In the case of any drug which, on the day immediately preceding the enactment date [October 10, 1962], (A) was commercially used or sold in the United States, (B) was not a new drug as defined by Section 201(p) of the basic Act as then in force [21 U.S.C. § 321(p)], and (C) was not covered by an effective [new drug] application under section 505 of that Act [21 U.S.C. § 355], the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

ADMINISTRATIVE PROCEDURE ACT

Section 10(e) of the Act, 5 U.S.C. § 706 provides as follows:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant

questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
SPARTANBURG DIVISION

Civil Action No. 76-1637

WILLIAM W. KING, JR.
and BROADUS ALLISON,
Intervenors,

IN RE:

JULIAN H. MORGAN, SR.
and JULIAN H. MORGAN, JR.,
Plaintiffs,

vs.

DAVID MATTHEWS, as Secretary of Department of Health, Education and Welfare; ALEXANDER M. SCHMIDT, Commissioner, Food and Drug Administration; and E. KENNETH AYCOCK, Commissioner, Department of Health and Environmental Control of State of South Carolina,
Defendants.

ORDER

This is an action to restrain the defendants from interferring with plaintiffs'-intervenors' [1] (hereinafter referred to as plaintiffs) procurement of a substance known variously as Laetrile, Amygdalin, Prunasin or Vitamin B 17; to obtain civil, criminal and ethical immunity for physicians, nurses and technicians, who would handle and administer this substance; and for a Rule to Show Cause why plaintiffs should not be allowed to procure the sub-

[1] The intervenors were made parties to the action by this Court's Order of October 19, 1976.

stance and place it in the hands of a licensed physician. The remaining defendants[2] have moved for dismissal of the action and for summary judgment on the grounds that the Court lacks subject matter jurisdiction of the action, because plaintiffs have failed to exhaust their administrative remedies, and even if there is jurisdiction, the plaintiffs have not and cannot meet the burden required of them to justify the injunctive relief requested.

The matter was heard by the Court on October 19, 1976 subsequent to its issuance of a Rule to Show Cause why plaintiffs should not be granted the relief requested in their motion for an immediate hearing.[3]

Since this is essentially a proceeding for a preliminary injunction, the provisions of Rule 52(a) of the Federal Rules of Civil Procedure dictate that the Court make the following

FINDINGS OF FACT

1. Amygdalin is the chemical name for Laetrile, a substance which occurs naturally in the kernels of apricots, peaches, bitter almonds and in other plant materials. It is a member of a class of substances known as cyanogenic glycosides. Laetrile or amygdalin is also commonly referred to as "Vitamin B-17" although any nutritional value it might have as a vitamin has not been established.

2. There is not currently on file nor has there ever been on file with the Food and Drug Administration an

[2] The defendant Aycock, Commissioner of South Carolina Department of Health and Environmental Control was dismissed from the case with plaintiffs' agreement on his motion for judgment on the pleadings.

[3] Plaintiffs moved for an immediate hearing stating inter alia, as grounds the gravity of plaintiff, Julian H. Morgan, Sr.'s condition and asking for essentially the same relief prayed for in their complaint, in particular a preliminary injunction to prevent the ICC and the Customs Department from interferring with plaintiffs' transportation of a temporary supply of Laetrile.

approved new drug application (NDA) permitting the distribution in interstate commerce of amygdalin for administration into the human body.

3. There is not currently on file with the Food and Drug Administration a Notice of Claimed Investigational Exemption (IND) permitting the investigational use of amygdalin in humans. An IND application was last made in 1970 by McNaughton Foundations of California which application was found inadequate and terminated shortly after it was received.

4. The plaintiff, Julian H. Morgan, Sr., was suffering from the advanced stages of cancer of the prostate and had from time to time used the substance in question, Laetrile, in an attempt to treat this disease and to mitigate its effects. On October 26, 1976, he died of the disease. The intervenor, Broadus Allison, is afflicted with cancer and seeks to use Laetrile to mitigate its effects.

CONCLUSIONS OF LAW

Initially the defendants' challenge this court's subject matter jurisdiction on the basis that plaintiffs have failed to exhaust their administrative remedies in that the drug has never been submitted to the Food and Drug Administration (FDA) for its approval and thus it has not had the opportunity to rule on the merits of such an application. In light of the Court's ruling on the preliminary injunction, it is not necessary at this time to consider this issue.

In considering whether the Court should grant a preliminary injunction, the plaintiffs have the burden of showing: (1) the probability that the plaintiff will succeed on the merits; (2) the threat of irreparable injury to the plaintiff should preliminary injunctive relief be denied; (3) the lack of injury to other parties should the injunction issue; and (4) the public interest will not be harmed by the granting of the preliminary relief sought.

Conservation Council of North Carolina v. *Costanzo*, 505 F. 2d 498, 502 (4th Cir. 1974); *Long* v. *Robinson*, 432 F. 2d 977, 979 (4th Cir. 1970). The plaintiffs have not met their burden with regard to these factors.

First, and most significantly, they have failed to show a substantial likelihood of success on the merits; specifically, that Laetrile is not a "drug" within the meaning of 21 U.S.C. § 321(g)(1) which defines it to be an article ". . . intended for use in the diagnosis cure, mitigation, treatment or prevention of disease in man . . . ." It is the intended use of substance which determines whether or not it is a "drug". *Hanson* v. *United States*, 417 F. Supp. 30, 34 (D. Minn. 1976), aff'd *Hanson* v. *United States*, No. 76-1156 (8th Cir. August 26, 1976). The evidence presented here indicates that Laetrile was intended to be used to treat the plaintiffs for cancer and to mitigate its effects. Accordingly, there is little likelihood of success on this issue. Furthermore, plaintiffs have not shown a substantial likelihood of success with respect to whether Laetrile is a "new drug" within the meaning of 21 U.S.C. § 321(p)(1) which defines it as "any drug . . . the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed . . . ." Plaintiffs have not shown a substantial likelihood of success in establishing that Laetrile is generally recognized as safe and effective by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

To the contrary, the defendants have presented substantial evidence, by affidavit and at the hearing, which shows that Laetrile is not generally regarded as safe and effective for use in the treatment of cancer.[4] Any

[4] Plaintiffs' own expert witness testified that it could not be said that Laetrile was *generally recognized* as safe and effective for use in the treatment of cancer; rather, it was recognized by a few. The defendants' expert testified that Laetrile was not recognized by those qualified by training and experience to be safe and effective for use in the treatment of cancer. This is supported by the affidavits submitted by the defendants. See Affidavit of Robert C. Eyerly, M.D. at 3; Affidavit of Vincent T. DeVita, Jr., M.D. at 4; Affidavit of George J. Hill, II, M.D. at 4; Affidavit of Carl M. Leventhal, M.D. at 3.

drug that is not *generally recognized* by qualified experts as safe and effective for its intended use is a new drug and cannot be shipped in interstate commerce until the information required by 21 U.S.C. § 355(b) is submitted for approval to the Secretary of Health, Education and Welfare in the form of a New Drug Application establishing that adequate and well controlled investigations have been performed to show that the drug is safe and effective, and the application is approved, 21 U.S.C. § 355. Here no NDA is or was in effect with respect to Laetrile.[5] See Finding of Fact 2, *supra*.

[5] Plaintiffs apparently contend that the burden is on the FDA to approve or disapprove of a new drug in the first instance, since they complain that the FDA "has failed, without adequate explanation, to approve Laetrile for distribution and use in the United States. . . ." The language and the history of the Act demonstrate that it is not the responsibility of the FDA to initiate applications on its own in the absence of an application that conforms with the statutory requirements of § 505(a) and (b). No such application has been filed here. *See* Finding of Fact 2, *supra*.

The FDA has been given the responsibility of "approving applications". Therefore, it is apparent that they must be submitted for approval. This conclusion conforms with the Act's legislative history.

The House Committee Report in discussion § 505 during its initial drafting in 1938 stated that

> This provision will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market.

H.R. Rep. No. 2139, 75th Cong., 3rd Sess. (April 14, 1938), p. 9. Further discussion was had as to this section in the House Report

The facts indicate that the administrative process has not been followed and since this would likely preclude an award of relief at the end of the litigation, the plaintiffs have not made a sufficient showing of the probability of ultimate success on the merits to obtain a preliminary injunction. *Wallace* v. *Lynn*, 507 F.2d 1186, 1189 (D.C. Cir. 1974).

It has not been shown that the plaintiffs will suffer irreparable harm if the injunction is not forthcoming. The only evidence presented to this Court of any benefit Laetrile might provide in the treatment of cancer is that in some instances individuals taking it "seem to experience diminishing pain and an increase in appetite, weight gain, and psychological improvement." Affidavit of Raymond Hilliard, M.D.[6] This is consistent with the effect a placebo would produce. The record is devoid of any evidence that Laetrile cures or halts the progress of cancer. Thus it does not follow that the enforcement of a law which denies Laetrile to a victim of cancer will cause him to suffer irreparable harm.

Finally, it has not been shown that the granting of injunctive relief in this case would not injure other parties or the public. To the contrary, to permit the distribution of Laetrile in this case would be to circumvent the laws enacted to assure that drugs distributed in interstate commerce be both safe and effective for their recommended use, and would undermine the ability of those charged

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of the 1962, amended version, which indicates that application was to be made by the manufacturer:

> Section 505 of the Food, Drug and Cosmetic Act prohibits interstate shipment of a "new drug" . . . unless it is first cleared for safety through the filing of a new drug application by the manufacturer.

H.R. Rep. No. 2464, 87th Con., 2d Sess. (Sept. 22, 1962), p. 3.

[6] Testimony to this effect was also given at the hearing by Dr. Hilliard and by the plaintiff Julian H. Morgan, Jr.

with upholding these laws to do so most effectively in the future. Such a holding would also provide any future proponent of unproven remedies a basis for arguing to another court that it should allow the distribution of substances in a manner contrary to the law.

This Court is not unmindful of the gravity of the situation facing those who are afflicted with cancer and of their desire to choose their own remedies in view of the absence of any known cure for this disease. However, granting the relief requested in this case could not only harm the public by weakening laws calculated to prevent the victimization of those afflicted with cancer and other conditions by playing on their desperation in the marketing of unproven and, possibly worthless remedies, but it could also further the growing tendency of those afflicted with this disease to engage in self treatment resulting in a delay in seeking eary diagnosis and prompt treatment with forms of therapy that have established value. The result of this type of delay could be disastrous, since early diagnosis and treatment is of the utmost importance in the management of cancer.[7]

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[7] This is support by most of the affidavits before the Court. See Affidavit of Robert C. Eyerly, M.D. at 3-4; Affidavit of Carl M. Leventhal, M.D. at 4.

> [P]roponents of Laetrile have advanced the argument that patients should be able to exercise free choice and select the drug if they wish to try it, despite a lack of scientific evidence of effectiveness. The idea that patients are able to make effective choices concerning cancer management without regard to existing evidence is dangerously misleading. Cancer management is a complex and demanding medical problem that depends upon availability of skilled trained physicians, surgeons, and other health professionals, and upon availability and use of drugs and other forms of therapy with defined and documented value. Availability and use of drugs which have not been found to have objective value makes no contribution to cancer management. It can, in fact, interfere with the very measures that are known to save lives by delaying diagnosis and effective treatment. The consequences of such delay may be needless and untimely death.

Affidavit of George J. Hill, II, M.D. at 3.

Accordingly, plaintiffs' prayer for preliminary injunctive relief is denied.

AND IT SO ORDERED.

ROBERT F. CHAPMAN
United States District Judge

November 30, 1976

Greenville, S.C.

APPENDIX B

VERDICT OF CORONER

(WITHOUT INQUEST)

IN THE MATTER OF THE DEATH OF

JO ANNE ETTA PYE Deceased.

I, C.R. Simmons, Coroner of Alameda County, do certify:

That on the 1st day of February 19 79, I investigated the circumstances surrounding the death of the above mentioned person, caused an examination and identification to be made of the body and find that deceased was named

JO ANNE ETTA PYE

a white female, ~~male, single, married, widowed~~, divorced, aged about 42 years; that ~~s~~he came to her death on the 3rd day of December 19 78 at Vesper Memorial Hospital, Emer.Room, San Leandro, Alameda County, California; and that death was caused by cyanide intoxication suffered at undetermined hours on December 3, 1978, at 14425 Birch Street, San Leandro, California.

Jo Anne Etta Pye, a carcinoma patient, ingested an amount of laetrile, causing cyanide intoxication.

Ethyl alcohol - - - 0% (blood).
Barbiturates - - - 0 MG% (blood).
Cyanide - - - - - 3.8 mcg/ml (blood) ; 0.8 mcg/ml (vitreous)
175 mcg (total gastric).
Diazepam - - - - - 0.3 mcg/ml (blood)
Desmethyldiazepam - 0 (blood).
Caffeine - - - - - 6.4 mcg/ml (blood).
All other toxicological tests were negative.

I find death ACCIDENTAL.

CODE: N.A.

Identified by Robert Pye, ex-husband.

Investigation by J.L. Shaw, Deputy Coroner.

Autopsy—~~Inspection~~ by P.M. Herrmann, M.D.

cc: San Leandro P.D., Att:Homicide
Inst. Forensic Sciences

IN WITNESS WHEREOF, I have hereunto set my hand this 1st day of February 19 79.

Charles R. Simmons

271-27

CERTIFICATE OF DEATH
STATE OF CALIFORNIA

78-2563

1a. NAME OF DECEDENT—FIRST: JoAnne	1b. MIDDLE: Etta	1c. LAST: Pye	2a. DATE OF DEATH: 12/3/78		2b. HOUR: 1730
3. SEX: Female	4. RACE: White	5. ETHNICITY: American	6. DATE OF BIRTH: February 11,1936	7. AGE: 42	
8. BIRTHPLACE OF DECEDENT: California	9. NAME AND BIRTHPLACE OF FATHER: Fred Hays, Missouri			10. MAIDEN NAME AND BIRTHPLACE OF MOTHER: Eva Boutwell	
11. CITIZEN OF WHAT COUNTRY: U. S. A.	12. SOCIAL SECURITY NUMBER	13. MARITAL STATUS: Divorced		14. NAME OF SURVIVING SPOUSE:	
15. USUAL OCCUPATION: Clerk	16. KIND OF BUSINESS: 5	17. EMPLOYED BY: Crescent Trucking Line		18. KIND OF INDUSTRY OR BUSINESS: Transportation	
19a. USUAL RESIDENCE: 14425 Birch St.		19b.		19c. CITY OR TOWN: San Leandro	
19d. COUNTY: Alameda	19e. STATE: Calif.	20. NAME AND ADDRESS OF INFORMANT—RELATIONSHIP: Robert Pye-Ex Husband 20111 30 Westridge Ct. Castro Valley, Calif. 94546			
21a. PLACE OF DEATH: Vesper Hospital #2	21b. COUNTY: Alameda				
21c. STREET ADDRESS OR LOCATION: 1800 Benedict Drive	21d. CITY OR TOWN: San Leandro				

CAUSE OF DEATH

22. DEATH WAS CAUSED BY: (ENTER ONLY ONE CAUSE PER LINE FOR A, B, AND C)
IMMEDIATE CAUSE (A): Cause under investigation
DUE TO, OR AS A CONSEQUENCE OF (B):
DUE TO, OR AS A CONSEQUENCE OF (C):

APPROXIMATE INTERVAL BETWEEN ONSET AND DEATH:

23a. WAS DEATH REPORTED TO CORONER? Yes
23b. WAS CORONER PERFORMED? no
23c. WAS AUTOPSY PERFORMED? yes

24. OTHER CONDITIONS CONTRIBUTING BUT NOT RELATED TO THE IMMEDIATE CAUSE OF DEATH:
25. WAS OPERATION PERFORMED FOR ANY CONDITION IN ITEMS 22 OR 24? TYPE OF OPERATION: DATE:

PHYSICIAN'S CERTIFICATION

26a. I CERTIFY THAT DEATH OCCURRED AT THE HOUR, DATE AND PLACE STATED. (FROM THE COURTS STATUS.)
26b. PHYSICIAN—SIGNATURE AND ADDRESS OR TITLE:
26c. DATE SIGNED:
26d. PHYSICIAN'S LICENSE NUMBER:
26e. TYPE PHYSICIAN'S NAME AND ADDRESS:

INJURY INFORMATION

27. SPECIFY ACCIDENT, HOMICIDE, ETC.:
28. PLACE OF INJURY:
29. INJURY AT WORK:
30a. DATE OF INJURY—MONTH, DAY, YEAR:
30b. HOUR:
31. LOCATION (STREET AND NUMBER OR LOCATION AND CITY OR TOWN):
32. DESCRIBE HOW INJURY OCCURRED (EVENTS WHICH RESULTED IN INJURY):

CORONER'S USE ONLY

33a. I CERTIFY THAT DEATH OCCURRED AT THE HOUR, DATE AND PLACE STATED FROM: "Investigation Pending" HELD AT (CORONER'S INVESTIGATION):
33b. SIGNATURE AND DESCRIPTIVE TITLE: Ronald Lang 133 Deputy Coroner
33c. DATE SIGNED: 12/4/78

34. DISPOSITION: cremation	35. DATE—MONTH, DAY, YEAR: 12-6-78	36. NAME AND ADDRESS OF CEMETERY OR CREMATORY: Irvington Memorial		37. EMBALMER'S LICENSE NUMBER AND SIGNATURE: 5335	
38. NAME OF FUNERAL DIRECTOR (OR PERSON ACTING AS SUCH): Herrero Mortuary Chapel	39. LOCAL REGISTRAR—SIGNATURE			40. DATE ACCEPTED BY LOCAL REGISTRAR	
STATE REGISTRAR: A.	B.	C.	D.	E.	F.

VS-11 10-78

AMENDMENT OF MEDICAL AND HEALTH SECTION DATA-DEATH

1a. FIRST NAME: JO ANNE	1b. MIDDLE NAME: ETTA	1c. LAST NAME: PYE	
2. PLACE OF OCCURRENCE—CITY OR COUNTY: Vesper Memorial Hospital, Emer. Room, San Leandro, Alameda County	3. DATE OF EVENT: 12/3/78	4. DATE ORIGINAL FILED	

ENTIFICATION OF THE RECORD

ORIGINALLY REPORTED FORMATION

INFORMATION AS REPORTED ON THE ORIGINALLY REGISTERED CERTIFICATE

22. DEATH WAS CAUSED BY: (ENTER ONLY ONE CAUSE PER LINE FOR A, B, AND C)
IMMEDIATE CAUSE (A): cause under investigation
DUE TO, OR AS A CONSEQUENCE OF (B):
DUE TO, OR AS A CONSEQUENCE OF (C):

APPROXIMATE INTERVAL BETWEEN ONSET AND DEATH:

24. WAS DEATH REPORTED TO CORONER? yes
25. WAS AUTOPSY PERFORMED? no
26. WAS AUTOPSY PERFORMED? yes

27. OTHER CONDITIONS CONTRIBUTING BUT NOT RELATED TO THE IMMEDIATE CAUSE OF DEATH:
28. WAS OPERATION PERFORMED FOR ANY CONDITION IN ITEMS 22 OR 24? TYPE OF OPERATION: DATE:

29. SPECIFY ACCIDENT, HOMICIDE, ETC.: ACCIDENT.
30. PLACE OF INJURY: residence
31. INJURY AT WORK: no
32a. DATE OF INJURY—MONTH, DAY, YEAR: 12/3/78
32b. HOUR: undeter.
33. LOCATION (STREET AND NUMBER OR LOCATION AND CITY OR TOWN): 14425 Birch St., San Leandro, Calif.
34. DESCRIBE HOW INJURY OCCURRED (EVENTS WHICH RESULTED IN INJURY): Caretaker patient ingested laqcrile. Alc.&carb.present. Cyanide:1.8 mcg/ml.

ORMATION IT SHOULD E STATED ON THE INALLY GISTERED RTIFICATE

INFORMATION AS IT SHOULD BE STATED ON THE ORIGINALLY REGISTERED CERTIFICATE

22. DEATH WAS CAUSED BY: (ENTER ONLY ONE CAUSE PER LINE FOR A, B, AND C)
IMMEDIATE CAUSE (A): cyanide intoxication.
DUE TO, OR AS A CONSEQUENCE OF (B):
DUE TO, OR AS A CONSEQUENCE OF (C):

APPROXIMATE INTERVAL BETWEEN ONSET AND DEATH:

24. WAS DEATH REPORTED TO CORONER? yes
25. WAS AUTOPSY PERFORMED? no
26. WAS AUTOPSY PERFORMED? yes

27. OTHER CONDITIONS CONTRIBUTING BUT NOT RELATED TO THE IMMEDIATE CAUSE OF DEATH:
28. WAS OPERATION PERFORMED FOR ANY CONDITION IN ITEMS 22 OR 24? TYPE OF OPERATION: DATE: no

29. SPECIFY ACCIDENT, HOMICIDE, ETC.: ACCIDENT.
30. PLACE OF INJURY: residence
31. INJURY AT WORK: no
32a. DATE OF INJURY—MONTH, DAY, YEAR: 12/3/78
32b. HOUR: undeter.
33. LOCATION (STREET AND NUMBER OR LOCATION AND CITY OR TOWN): 14425 Birch St., San Leandro, Calif.
34. DESCRIBE HOW INJURY OCCURRED (EVENTS WHICH RESULTED IN INJURY): Caretaker patient ingested laqcrile. Alc.&carb.present. Cyanide:1.8 mcg/ml.

LARATION OF TIFYING YSICIAN CORONER

35. I THE UNDERSIGNED PHYSICIAN OR OTHER AUTHORIZED PERSON, DECLARE OF SUPPLEMENTAL INFORMATION WHICH MODIFIES THE INFORMATION ORIGINALLY REPORTED BELOW. I DECLARE UNDER PENALTY OF PERJURY THAT THE ABOVE INFORMATION IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.
35a. SIGNATURE: Charles R. Simmons
35b. DEGREE OR TITLE: Coroner
35c. ADDRESS: 480-4th St., Oakland, California.
35d. DATE SIGNED: 2/1/79

STRAR'S FICE

36. OFFICE OF STATE OR LOCAL REGISTRAR
36a. DATE ACCEPTED

STATE OF CALIFORNIA—DEPARTMENT OF HEALTH SERVICES — FORM VS-24B (REV. 10-78)

LAST NAME	FIRST NAME	MIDDLE NAME	CLASSIFICATION	CASE NUMBER
PYE	Joann		Natural	78-2563

AKA

DATE OF BIRTH	DATE REPORTED	TIME REPORTED	REPORTED TO
11 Feb 1936	12-3-78	1740	ATF

SEX	AGE	COLOR	WEIGHT	HEIGHT	EYES	HAIR	NATIV	SOCIAL STATE	OCCUPATION	REMOVED BY	ON DUTY DEATH
Fe	42	Cau	116	62	Brn	Brn		Divorced	At Home	JLS/gj	NO

DATE DEATH	TIME DEATH	DATE FOUND	TIME FOUND	EST DATE DEATH	FOUND BY	RELATIONSHIP
12-3-78	1730					

PLACE OF DEATH	CITY	COND PREMISES	RECEIPT NO	DISPOSITION BODY
Vesper Memorial Hospital ER	S/Leandro	Hospital	44968	NONE

RESIDENCE OF DECEASED	CITY	STATE	CONDITION BODY	RIGOR DEGREE	P/M'L
14425 Birch Street 352-6851	S/Leandro	Calif.	BreastCA	Slight	Present

FUNERAL DIRECTOR	CITY	STATE	BODY TEMP	POLICE SCENE	DEPARTMENT
Guerrero Mortuary JK Scott			Warm	NO	S/L PD

NEXT OF KIN, POLICE INFORMANTS - WITNESSES MEDICAL PERSONNEL

RELATIONSHIP	NAME		ADDRESS	CITY OR TELEPHONE
EX-HUSB	PYE, Robert R.	582-8439	20111 Westridge Ct. #30	C/Valley
DOCTOR	BRIDE, Francis (pronounced)		Vesper Mem Hospital	
NURSE	SHARP, Robin RN	(I)	Vesper Mem Hospital	

MEDICAL SUMMARY TREATMENTS - MEDICATION INJURIES - DIAGNOSIS

Private physician _____ M.D. (will) (will not) sign death certificate.

CANCER OF THE BREAST

Dec last seen by a Dr HESS in Chula Vista (714 421-0584) 10 weeks ago. She was also treated at the Richardson Clinic in Albany, in Mexico and the Philippines. Dec went into convulsions at home just prior to admit to ER. On special diet of natural foods and juices.

PARTICULARS SURROUNDING DEATH (details, equipment in use, circumstances at, and leading to death.)

FAMILY (relationship) of deceased notified on 12-3-78 (date) at _____ (time) via Hospital (means)

The Dec was brought to the ER at 1707 hours via police ambulance: she was pronounced at 1730 hours by Dr. Bride - the ER chart had a notation of 'essentially DOA'. Just prior to the calling of the ambulance, the Dec had gone into a state of convulsions. She had a history of cancer of the breast - diagnosed in various places - refused to have any type of operation.

The ex-husband reports that the Dec was probably last seen about ten weeks ago by her doctor in Chula Vista; she had no PMD in the local area. The Dec had been treated in Mexico and in the Philippines and had consulted various spiritual and faith healers. She was also treated in Albany at the Richardson Clinic. The Dec was being taken care of by a Gail WALZ who reports that the Dec was on a diet of natural foods and juices. She was taking various other medications prescribed by Dr. HESS including the medication made from apricot pits.

J.L. Shaw

INVESTIGATOR'S REPORT
Alameda County Coroner's Department
Alameda County, California

Investigator:					
INVESTIGATION TIME FROM:	1800	TO	1845	TOTAL TIME	.45
REPORTS TIME FROM:	2015	TO	2030	TOTAL TIME	.25

LAST NAME	FIRST NAME	MIDDLE NAME	CLASSIFICATION	CASE NUMBER
PYE	JoAnn		Natural	78-2563

INFORMANT NAME	ADDRESS	CITY OR TELEPHONE
KETTNER, JoAnna	Richardson Center-514 Kains Ave.	Albany, Ca. 527 3020
BRODIE, W. D.	"	"

ILARS 12-05-78 1230 hrs.

ne above (I) gave the following information: Dec'd initally seen in their clinic in March f '78. Meds include "tetracycline, tamoxifen (discontinued), percobarb, dilaudid, id laetrile. Dec'd had been seen by Dr. A.B. CAMERON (dept. of surgery) in March of '78 t Kaiser Hosp. in Hayward. A biopsy performed at Eden Hosp. "infiltrating adeno arcinoma of left breast".

Dispensing of laetrile: In the beginning dec'd was given 9 Grams (30cc) everyday for 20 days started 3-21-78); Then 3 Grams (10cc) given 3 times a week for a month, then 2 times a eek for a month, then 1 time a week (each dosage was 3 Grams or 10cc) for at least 18 onths (dec'd never completed last stage). Last injection dec'd received was on Sept. 9th of '78. If the dec'd is unable to receive her weekly injection she takes a tablet f laetrile (1000 mgm)..R/P does not know how many tablets the dec'd may have had on her erson . When the dec'd returned home from the PI she was very depressed over prices id cost of food; loss of sleep associated with severe pain. Dec'd last seen at theclinic the 28th of Aug., 1978. Laetrile tablets ordered through Mexico with anaffidavit.

SUPPLEMENTAL

INVESTIGATOR'S REPORT
Alameda County Coroner's Department
Alameda County, California

Investigator:	IIIA #136		
INVESTIGATION TIME FROM:	Allen #134 TO		TOTAL TIME
REPORTS TIME FROM:	TO		TOTAL TIME

COUNTY OF ALAMEDA

OFFICE OF
CHARLES R. SIMMONS
CORONER-PUBLIC ADMINISTRATOR-PUBLIC GUARDIAN
CONSERVATOR
480 - 4TH STREET
OAKLAND, CALIFORNIA 94607

PUBLIC ADMINISTRATOR
PHONE: 874-6741

PUBLIC GUARDIAN-CONSERVATOR
PHONE: 874-6741

CORONER'S DIVISION
PHONE: 874-5551

cc: Vesper Memorial Hospital ER

Coroner
Alameda County

Body of JO ANNE ETTA PYE

Autopsy performed upon the body of JoAnne Etta Pye at the Coroner's Office, 480 - 4th Street, Oakland, California, on December 4, 1978, at 10:00 a.m., by Paul W. Herrmann, M.D.

ANATOMICAL DIAGNOSES

1) CARCINOMA OF THE LEFT BREAST.

2) METASTASES TO THE LEFT AXILLARY LYMPH NODES, INTERNAL MAMMARY LYMPH NODES, AND INVASION OF THE CHEST WALL.

3) CARCINOMA OF THE RIGHT BREAST, PROBABLY METASTATIC.

4) CARCINOMA INVOLVING THE SOFT TISSUE OF THE RIGHT AXILLA.

5) ACUTE CONGESTION AND EDEMA OF THE LUNGS.

6) ACUTE CONGESTION OF THE LIVER AND KIDNEYS.

7) CYANIDE ODOR TO THE BODY CAVITY.

8) FATTY CHANGE OF THE LIVER.

CAUSE OF DEATH: CYANIDE INTOXICATION.

78-2563

APPENDIX C

COMMONWEALTH OF MASSACHUSETTS

SUPERIOR COURT

Civil Action No. 78-6816

PLYMOUTH, SS.

CUSTODY OF A MINOR

ORDER

The attorney for the child and the Attorney General have petitioned this Court to hold the parents in civil contempt as a result of the actions of the parents in removing the child from the Commonwealth of Massachusetts. Based on the stipulated evidence that the parents have in fact removed the child from the Commonwealth, and based on the fact that the parents are represented at this hearing by counsel, I find the parents to be in civil contempt of court for their violation of the Order that was entered on April 18, 1978 and that was incorporated into the Order entered on January 22, 1979, which directed that the child be treated by any board certified pediatric hematologist within the Commonwealth of Massachusetts. I continue the hearing to Wednesday, February 7, 1979, to permit the parents to cure the contempt.

The Court wishes to emphasize the ability of the parents to purge themselves of this contempt and thereby to avoid being subject to any penalty by returning the child to the Commonwealth of Massachusetts and complying fully thereafter with the Court's orders.

The Court has accepted into evidence today a new laboratory test which indicates a level of free cyanide in the child's blood at twice the normal level. In light of this

new evidence of chronic cyanide toxicity, and in light of the Court's belief that the parents share the Court's deep concern for the safety and well-being of the child, I would hope and expect that the parents will appreciate the medical and legal advisability of returning the child to the skilled supervision of a Massachusetts medical center—both to avoid being penalized for their contempt and to maximize the child's chances of being cured.

/s/ Guy Volterra
GUY VOLTERRA, DCJ
(Sitting by Statutory Designation)

Dated: January 31, 1979

COMMONWEALTH OF MASSACHUSETTS

SUPERIOR COURT

Civil Action No. 78-6816

PLYMOUTH, SS.

CUSTODY OF A MINOR

INTERLOCUTORY ORDER

As the Court finds, after extensive hearing, that the parents have been administering to the minor child an unapproved drug, Amygdalin (Laetrile), which is dangerous to health, and that the parents have also been giving the minor child without medical supervision and prescription megadoseages of Vitamins A and C, mineral supplements, enzymes, folic acid, and calcium lactate, and as the Court further finds that the administering of these substances and drugs has been against the specific advice of the treating physician; the Court finds that the conduct of the parents in administering these substances to the minor child is harmful to the health of the child and may be counter-productive to the medical treatment the child is currently receiving for acute lymphocytic leukemic. The Court, until entry of a Final Order, issues the following Interlocutory Order:

1. The Order of this Court for Care and Protection dated April 18, 1978 is hereby continued in force; and

2. The parents are hereby ordered to cease administering to the minor Amygdalin (also known as Laetrile, Vitamin B-17, Kemdalin, and other trade names) by tablet or injection to the minor; and

3. The parents are hereby ordered to cease administering to the minor Vitamin A and Vitamin C in any form and in any amounts except that which the minor

child may ingest from the diet recommended by the treating physicians; and

4. The parents are hereby ordered to cease administering to the minor enzyme enemas; and

5. The parents are hereby ordered to cease administering to the minor any mineral supplements, enzymes, folic acid, or calcium lactate unless the administration of such substances is first approved by the treating physician; and

6. The parents are ordered to submit the minor to such urine thiocyanate and serum thiocyanate tests as are ordered by the treating psysician. The treating physician shall report to the Court any test results which indicate to him that the child remains at risk of chronic cyanide poisoning; and

7. The parents are ordered to submit the minor to such Vatimin A and liver function tests including SGOT, as are ordered by the treating physician to test for hypervitaminosis A and liver functions. The treating physician shall report to the Court any test results which indicate to him that the child remains at risk of hypervitaminosis A and impaired liver function.

8. The parents are to obtain from the treating physician a recommended diet prepared by a dietician which is nutritionally sound and which is to reflect the parents stated preference for natural foods which are free from additives and preservatives.

By the Court,

/s/ Guy Volterra
GUY VOLTERRA, D. C. J.
Sitting by Statutory
Designation

Dated: January 22, 1979

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

No. K 77-1283

UNITED STATES OF AMERICA,
Plaintiff,

v.

Articles of drug consisting of the following:

45 bottles (vials), more or less, and 47 bottles (vials) more or less, labeled in part:

(bottle (vial))

"Amigdalina Cyto Pharma * * * 250 Comprimidos * * * 500 mg. * * * Mexico"

(tablet)

Embossed on one side with "500" and other side is with a score mark and a pine tree logo.

23 boxes, more or less, and 25 boxes, more or less, each containing 100 ampuls, more or less, labeled in part:

(ampul)

"Amigdalina Cyto Pharma 10 ml. * * * Cyto Pharma De Mexico S.A."

Defendant.

COMPLAINT FOR FORFEITURE

To The Honorable Judge of the United States District Court For The District of Maryland.

Now comes the United States of America by Jervis S. Finney, United States Attorney for the District of Maryland, and shows to the Court:

1. That this complaint is filed by the United States of America, and prays seizure and condemnation of certain articles of drug, as hereinafter set forth, in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

2. That this Court has jurisdiction under 28 U.S.C. 1345 and 21 U.S.C. 334.

3. That there are at Baltimore, Maryland, in the possession of Henderson's Pharmacy, 7401 Harford Road, and Robert W. Henderson, 5 Weyburn Court, Baltimore, Maryland, or elsewhere within the jurisdiction of this Court, the articles of drug hereinabove described in the caption of this matter, which articles were shipped in interstate commerce on or about July 12, 1977 (47 bottle (vial) and 23 box lots) and on or about July 21, 1977 (45 bottle (vial) and 25 box lots), by Cyto Pharma, from Tijuana, Mexico into California via known carriers; and subsequently delivered to Robert W. Henderson in Baltimore, Maryland.

4. That the aforesaid articles are new drugs within the meaning of 21 U.S.C. 321(p)(1), which may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. 355(a), since no approval of an application filed pursuant to 21 U.S.C. 355 (b) is effective with respect to such drugs; no notice of claimed investigational exemption pursuant to 21 U.S.C. 355(i) and regulation 21 CFR 312.1 is on file for such drugs; and the drugs are not exempt from the requirements of the new drug provisions of said act, 21 U.S.C. 355, pursuant to the order of the Court in *Rutherford* v. *United States*, 429 F. Supp. 506 (W.D. Okla., 1977), since the articles were offered for importation into the United States solely for the personal use and benefit of persons who executed affidavits required by the Court in *Rutherford* and are intended for distribution to persons other than those for whose benefit the articles were imported.

5. That the aforesaid articles were adulterated when introduced into and while in interstate commerce, within the meaning of said Act, 21 U.S.C. 351(a)(2)(B) in that they are drugs and the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice, as set forth in regulations 21 CFR 211, to assure that such drugs meet the requirements of said Act as to safety and have the strength and meet the quality and purity characteristics which they purport and are represented to possess.

6. That the aforesaid article (47 bottle (vial) lot) was adulterated when introduced into, while in, and while held for sale after shipment in interstate commerce, within the meaning of said Act, 21 U.S.C. 351(c), in that it is a drug not subject to the provisions of 21 U.S.C. 351(b) and its strength differs from that which it purports and is represented to possess, because it contains less than 500 milligrams of amygdalin.

7. That the aforesaid articles were misbranded, when introduced into, while in, and while held for sale after shipment in interstate commerce, within the meaning of said Act, 21 U.S.C. 352(j), in that Amigdalina (amygdalin) tablets are dangerous to health when used in the manner, and with the frequency and duration prescribed, recommended and suggested in the labeling thereof, that is, when used orally and with the frequency and duration prescribed in affidavits which are accompanying labeling for the tablets.

8. That by reason of the foregoing, the aforesaid articles are held illegally within the jurisdiction of this Court, and are liable to seizure and condemnation.

WHEREFORE, plaintiff prays that process in due form of law according to the course of this Court in cases of actions in rem issue against the aforesaid articles; that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this Court decree the condemnation of the aforesaid articles and grant plaintiff the costs of this proceeding against the claimant of the aforesaid articles; that the aforesaid articles be disposed of as this Court may direct pursuant to the provisions of said Act; and that plaintiff have such other and further relief as the case may require.

UNITED STATES OF AMERICA

By: /s/ Jervis V. Finney
United States Attorney

/s/ Gerard P. Martin
GERARD P. MARTIN
Assistant United States Attorney

8/4/77

I certify under penalties of perjury that the facts contained in the aforesaid complaint are accurate and true to the best of my knowledge and belief.

/s/ Gerard P. Martin
GERALD P. MARTIN
Assistant United States Attorney

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

No. K-77-1283

UNITED STATES OF AMERICA,
Plaintiff,

v.

Articles of drug consisting of the following:

45 bottles (vials), more or less, and 47 bottles (vials) more or less, labeled in part:

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(ampul)

"Amigdalina Cyto Pharma 10 ml. * * * Cyto Pharma De Mexico S.A."

Defendant.

MOTION FOR PARTIAL RELEASE OF SEIZED GOODS AND SUPERVISED DELIVERY TO CERTAIN PATIENTS

Now comes the United States of America, plaintiff herein, and moves this Honorable Court for release of certain ampoules and tablets of the drug Laetrile, as hereinafter specified, which were seized by the United States Marshal on August 5, 1977 pursuant to motion of

the Court. The order prayed for seeks release from the United States Marshal of limited amounts of the drug for redelivery to Robert Henderson, R.Ph., 7401 Harford Road, Baltimore, Maryland, in order that Mr. Henderson, under supervision of authorized agents of the United States Food and Drug Administration, cause to be delivered to patients entitled to receive Laetrile the amount of said drug they ordered. As grounds for this motion plaintiff states that:

1. Pursuant to procedures authorized by the Court in *Rutherford* v. *United States*, 429 F. Supp. 506 (W.D. Okla., 1977), persons diagnosed as suffering from terminal cancer may import for their personal use only a limited amount of Laetrile not to exceed 750 tablets and 150 10cc ampoules. As a condition precedent to importation the patient or his duly authorized agent must present to the United States Customs Service an affidavit of a physician certifying the patient's condition and specifying the amount of Laetrile ordered.

2. On July 12, 1977 affidavits for 16 patients were presented to customs officials to justify importation of 2,380 ampoules and 11,950 tablets of Laetrile. These articles were thereafter shipped to Robert Henderson.

3. On July 21, 1977 affidavits for 17 patients were presented to customs officials to justify importation of 2,450 ampoules and 11,150 tablets of Laetrile. These articles were thereafter shipped to Robert Henderson.

4. As agent for the persons named in the affidavits, Mr. Henderson was authorized to deliver to these persons the amounts of Laetrile imported on their behalf and for their personal use.

5. Investigations by United States Food and Drug Administration investigators have revealed that the affidavits are fraudulent in that patients on whose behalf affidavits were presented to customs officials either ordered significantly less than the amount of Laetrile declared on the affidavits or did not order any Laetrile whatsoever and are unaware of any affidavit being executed on their behalf.

6. Food and Drug Administration investigations further reveal that Mr. Henderson has solicited abandonment of Laetrile from patients who ordered Laetrile and on whose behalf affidavits were presented to customs officials and that either as a result of such solicitations or for other reasons, some patients have cancelled or reduced their orders for Laetrile.

7. Food and Drug Administration investigations further reveal that affidavits presented to customs officials contain false information in that the amounts of Laetrile represented to have been ordered by the patients exceeds the amounts actually ordered and that Mr. Henderson uses these amounts of Laetrile not ordered by patients to create a stockpile from which he then sells to other persons who have not executed affidavits presented to Customs for purposes of facilitating importation of the drug for their use.

8. Patients on whose behalf Laetrile was lawfully imported into the United States pursuant to procedures prescribed in *Rutherford* v. *United States*, *supra*, have supplied FDA investigators with information concerning the amounts of Laetrile they ordered and still desire to be delivered to them. In the aggregate the total amount of Laetrile they ordered and desire to receive is *77* ampoules and *280* tablets.

The Food and Drug Administration is in the process of contacting other patients to determine the amounts of Laetrile they ordered and still desire to obtain and will report promptly its finding to this Court.

Wherefore, the United States prays that the Court enter the attached proposed Order for Partial Release of Seized Goods and Supervised Delivery to Certain Parties.

Respectfully submitted,

JERVIS S. FINNEY
United States Attorney

By: _____
NEAL JANEY
Assistant United States Attorney

Of Counsel:

STEPHEN H. MCNAMARA
Acting Chief Counsel

EUGENE M. PFEIFER
Associate Chief Counsel
for Enforcement

Office of the General Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857